C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF **MONTREAL**

No.: 500-06-001254-230

(Class Actions)
S U P E R I O R C O U R T

HERBERT "TROY" DINGWELL

Plaintiff

v.

ADVANCED BIONICS L.L.C.

and

ADVANCED BIONICS AG

and

SONOVA HOLDING AG

and

SONOVA AG

and

SONOVA CANADA INC.

Defendants

and

RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC

and

ATTORNEY GENERAL OF QUEBEC

Interveners

ORIGINATING APPLICATION IN A CLASS ACTION
(Articles 141 and 583 *CCP*)

TO THE HONOURABLE MARIE-CHRISTINE HIVON, JUDGE OF THE SUPERIOR COURT ASSIGNED TO MANAGE THIS CLASS ACTION PROCEEDING, THE PLAINTIFF RESPECTFULLY SUBMITS THE FOLLOWING:

I. OVERVIEW

1. Cochlear implants are electronic devices that allow individuals who are severely to profoundly deaf to process sounds. These devices are surgically implanted in a part of the inner ear called the cochlea.

2. The Defendants developed, manufactured and sold cochlear implants under the names “HiRes Ultra” and “HiRes Ultra 3D” - the initial “versions” of these implants (hereafter, the “**Cochlear Implants**”) were sold and implanted in Canada between 2017 and 2020.

3. The Cochlear Implants are defective and were recalled by the Defendants in February 2020. Fluid enters the surgically implanted electrode, causing degradation and/or loss of function. This defect can also cause physical symptoms such as pain, nausea, dizziness, and convulsions. An excessively high number of the Cochlear Implants have already required replacement surgery, and many more will require such surgery in the future.

4. The Defendants knew that the Cochlear Implants posed major risks, as they were a “repackaging” of a previous model that had been recalled on several occasions for the same defect. Furthermore, once the Defendants received confirmation that the Cochlear Implants were failing, they neglected to recall the devices in a timely manner – instead, they developed a new “version” of the “HiRes Ultra” series, and only recalled the Cochlear Implants once this new version was ready to bring to market.

5. For the reasons, the Defendants are liable for the injuries caused to class members by the safety defects of the Cochlear Implants, and must also be ordered to pay these class members punitive damages.

II. AUTHORIZATION OF THE CLASS ACTION

6. On February 27th, 2025, this Court rendered a judgment authorizing the Plaintiff to institute the present class action against the Defendants and appointing him as class representative (the “Authorization Judgment”). As appears from the Court record, the Defendants consented to authorization of the class action (without admission) following modifications to the authorization application approved by this Court by a judgment rendered on October 11th, 2024.

7. In the Authorization Judgment, the Court defined the class as follows:

> All persons who were implanted in Québec with a HiRes Ultra or HiRes Ultra 3D cochlear implant manufactured by Advanced Bionics bearing serial numbers between 1000000 and 1999999, or any components of such cochlear implants including the electrode array.
>
> All persons who are the successor, spouse, parent, child, sibling, dependant or caregiver to a person described in the preceding paragraph.
>
> *Toutes les personnes qui se sont fait implanter, au Québec, un implant cochléaire de modèle « HiRes Ultra » ou « HiRes Ultra 3D » fabriqué par Advanced Bionics portant un numéro de série entre 1000000 et 1999999, ou toute composante d’un tel implant cochléaire incluant le porte-électrodes.*

Toutes les personnes qui sont l'héritier, le conjoint, le parent, l'enfant, le frère, la sœur, la personne à charge ou l'aidant naturel d'une personne visée par le paragraphe précédent.

(hereafter, collectively, the "**class members**")

8. The authorization judgment identified the following questions of fact and law to be decided collectively on the merits of the present class action:

    a. Do the HiRes Ultra and HiRes Ultra 3D cochlear implants bearing serial numbers between 1000000 and 1999999 contain a safety defect?

    b. If so, did this safety defect cause injuries to class members?

    c. If so, can the Defendants avoid liability by reason of one of the means of defence found at art. 1473 *CCQ*?

    d. Did the Defendants breach class members' right to personal security protected by the *Charter of Human Rights and Freedoms* in the context of the manufacturing, pre-market testing, marketing and/or post-market surveillance of the Cochlear Implants? If so, was this breach illicit and intentional?

    e. Can the Court order collective recovery of the non-pecuniary and punitive damages due to class members?

III. THE PARTIES

A. The Defendants

9. Advanced Bionics LLC is a company incorporated in the state of Delaware, USA and headquartered in Valencia, California, USA. It carries on the business of the design, testing, manufacturing, marketing, sale and post-sale monitoring of cochlear implants, including the HiRes Ultra and HiRes Ultra 3D Cochlear Implants. It is a wholly owned subsidiary of the Defendant Sonova Holding AG. The Plaintiff files in this regard excerpts of the "Annual Report 2024-2025" for the Sonova Group as **Exhibit P-1**.

10. Advanced Bionics AG is incorporated and headquartered in Switzerland and was registered with Health Canada as the manufacturer of the Cochlear Implants. It is also a wholly owned subsidiary of Sonova Holding AG, as appears from Exhibit P-1.

11. Sonova Holding AG is incorporated in Switzerland. As appears from the Annual Report, Exhibit P-1, Sonova Holding AG is the ultimate parent company of the consolidated Sonova Group, and the only company in this group to be publicly traded (it is listed on the SIX Swiss Exchange). As also appears from Exhibit P-1, Sonova Holding AG holds 100% (directly or through subsidiaries) of the shares of all the other defendant corporations. Sonova Holding AG acquired the parent

corporation of Advanced Bionics LLC in 2010, thereby entering the cochlear implant industry. At all relevant times, the Cochlear Implants were manufactured and brought to market under the Advanced Bionics brand name.

12. Sonova AG is incorporated in Switzerland. As appears from the Annual Report, Exhibit P-1, Sonova AG is involved in the holding/finance, sales, production and research of the Sonova Group. It is a wholly owned subsidiary of Sonova Holding AG.

13. Sonova Canada Inc. is a company incorporated under Ontario's *Business Corporations Act*[1] with a head office in Mississauga, Ontario, as appears from its information on the *Registre des entreprises du Québec*, **Exhibit P-2**. As appears from Exhibit P-1, this company is involved in sales and marketing activities.

14. The Defendants committed all of the acts alleged below in concert, in pursuit of a common business plan. They conducted their operations as a single global business organization, in order to promote the business of cochlear implants carried out under the Advanced Bionics brand name ("**Advanced Bionics**" is used hereafter interchangeably with "**the Defendants**"). They shared officers and directors and issued joint annual reports and consolidated financial statements. More specifically:

    a. As stated in Sonova Holding AG's Annual Report for 2024-2025, Exhibit P-1 (excerpts), the Sonova Group's "businesses are deeply connected […] They collaborate in R&D, manufacturing, marketing, sales, and customer support […]" More specifically:

    b. The year the Cochlear Implants were brought to market, Sonova Holding AG's "Management Board" included a "Group Vice President Cochlear Implants", Hansjürg Emch, as appears from Sonova Holding AG's Annual Report for 2016-2017 (excerpts), **Exhibit P-3.**

    c. Since July 2024, Alistair Simpson, President of Advanced Bionics, has acted as Group Vice President Cochlear Implants for Sonova Holding AG, as appears from Exhibit P-1.

    d. As appears from the "Segment Information" and "List of Significant Companies" contained in Exhibit P-1, research and development and marketing activities for the Advanced Bionics business segment is undertaken in both the United States and Switzerland by the corporate entities named as Defendants.

B. The Plaintiff

15. The Plaintiff, Herbert "Troy" Dingwell lived in Lac-Saguay, Québec between 2015 and 2020. He currently resides in Golden Lake, Ontario.

[1] RSO 1990, c B.16.

16. The Plaintiff was implanted with a Cochlear Implant on his left side in 2017 at the CHU de Québec – Université Laval.

17. As detailed below, the Plaintiff's Cochlear Implant failed such that he was forced to undergo revision surgery on October 8, 2024, at the Ottawa Hospital.

IV. THE FACTS GIVING RISE TO AN ACTION FOR THE PLAINTIFF AND EACH MEMBER OF THE GROUP

A. Cochlear implants

18. Cochlear implants are devices that provide hearing to deaf or hard-of-hearing individuals. They are designed for patients who have severe hearing loss from inner-ear damage who are not able to benefit from hearing aids, as well as patients who are congenitally deaf.

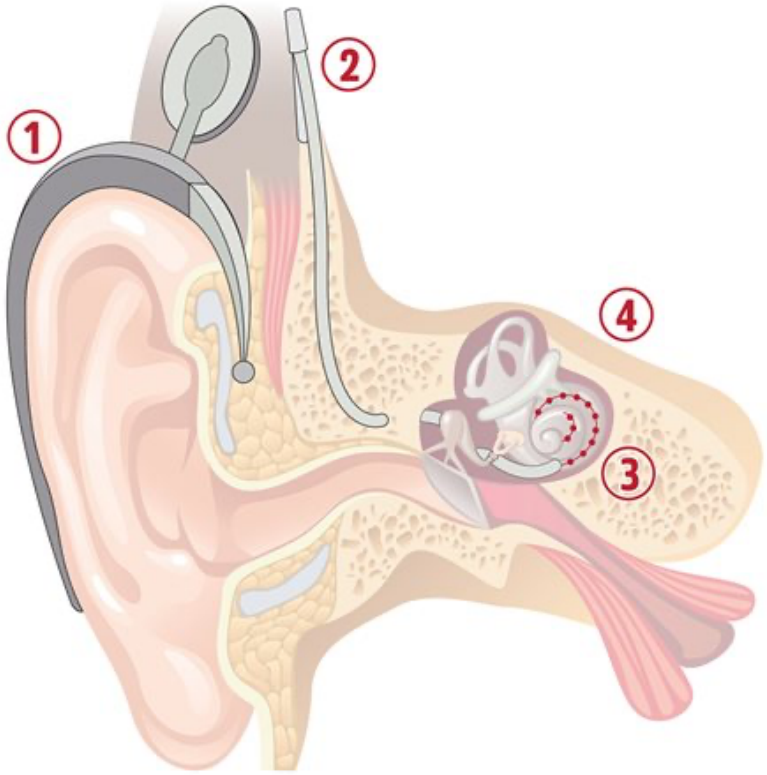
19. Both adults and infant children can receive cochlear implants. As pediatric patients are still developing their auditory cortex, a properly functioning cochlear implant is critical for higher-level linguistic and cognitive development and function.

20. Unlike a hearing aid, which amplifies sound, a cochlear implant delivers sound signals directly to the auditory nerve. A sound processor captures sound signals and digitally processes them, sending them to a receiver under the skin behind the ear. The receiver sends these signals to electrodes implanted in the snail-shell shaped inner ear (the cochlea), stimulating the acoustic (or cochlear) nerve.

21. While the external sound processor typically needs replacement every five to ten years, the internal implant is meant to last a lifetime.

22. Cochlear implant surgery is a major medical procedure, both physically and in terms of recovery time. Patients must undergo intensive functional rehabilitation – including follow-up with medical doctors, audiologists, psychosocial interveners and speech-language pathologists – in order to learn how to interpret the signals generated by the implant. Such rehabilitation typically lasts up to 10 weeks for adults and up to 12 weeks for children.

Fig. 1 – Basic functioning of cochlear implants



Fonctionnement de l'implant cochléaire

1. Le microphone capte les sons de l'environnement. Ensuite, les sons sont analysés par le processeur.
2. Les sons codés sont transmis à la partie interne. Celle-ci les transforme en impulsions électriques.
3. Les impulsions électriques sont dirigées vers les électrodes.
4. Les électrodes stimulent le nerf auditif qui envoie l'information au cerveau.

* Source: CHU de Québec – Université Laval; accessed on July 31, 2023 at: https://www.chudequebec.ca/patient/maladies-soins-et-services/specialites-et-specialistes/specialites/implant-cochleaire.aspx

B. The HiRes Ultra Cochlear Implants are defective

23. The first versions, or "V1" models of the HiRes Ultra and HiRes Ultra 3D Cochlear Implants were introduced by Advanced Bionics in 2016.

24. The HiRes Ultra Cochlear Implant received approval from Health Canada on February 20, 2017, as detailed in a press release issued on Business Wire, **Exhibit P-4**. The device was promoted as featuring a low profile, making it ideal for recipients of all ages.

25. The HiRes Ultra 3D Cochlear Implant received approval from Health Canada on April 8, 2019, as detailed in a press release issued on Business Wire, **Exhibit P-5**.

26. Globally, Advanced Bionics reports that there have been 12,553 HiRes Ultra "V1" and 6,697 HiRes Ultra 3D "V1" Cochlear Implant surgeries, as detailed in Advanced Bionics' Reliability Report from July 2024, **Exhibit P-6**. According to information obtained from the *Régie de l'assurance-maladie du Québec*, 164 such implant surgeries were performed in the province.

27. On February 17, 2020, Advanced Bionics announced a recall of all non-implanted "V1" Cochlear Implant models, citing "hearing performance degradation due to body fluid entering the device", as appears from an entry in the United States Food and Drug Administration's (hereafter, the "**FDA**") database for medical devices, **Exhibit P-7**.

28. On April 17, 2020, Health Canada published a Medical Device Recall for the Cochlear implants – a copy of this publication is attached as **Exhibit P-8**.

29. In December 2022, a study published in the medical journal *The Laryngoscope* by world-renowned specialists Dr. Lutz Gärtner and Dr. Thomas Lenarz showed the dramatic extent of the defect affecting the Cochlear Implants. The article, titled "Advanced Bionics HiRes Ultra and Ultra 3D Series Cochlear Implant Recall: Time Course of Anomalies", is attached as **Exhibit P-9**.

30. Between September 2016 and October 2019, Drs. Gärtner and Lenarz implanted 349 Cochlear Implants at their clinic in Hannover, Germany, in the context of a clinical study conducted for Advanced Bionics. Representatives of Advanced Bionics were on site at the clinic, and tested devices suspected of malfunction using proprietary electrical field imaging (hereafter, "**EFI**") software.

31. More specifically, implantation of the HiRes Ultra devices took place between September 2016 and November 2018, and implantation of the HiRes Ultra 3D devices took place between November 2018 and October 2019.

32. As detailed in their study, as of March 2022, more than 50% of the implanted Cochlear Implants showed anomalies, and nearly 35% of them had already required revision surgery to replace them. The study also concluded that the median survival time without anomalies of the devices – that is, the average time it took for the devices to fail – was 1,062 days.

33. The failure was caused by fluid ingress near the ring electrode of the Cochlear Implants. When fluid moves into the electrode pocket of the devices, the function of the electrodes is impeded, leading to decreased function. As a result, patients experienced distorted sound and impaired speech comprehension.

34. Each explanted Cochlear Implant was given by Drs. Gärtner and Lenarz's team to Advanced Bionics, who conducted individual device failure analyses (hereafter, "**DFA**"). At the time of publishing their study, 76 of the 80 completed DFAs had

revealed that the reason for the device failure was a short-circuit caused by fluid ingress in the electrode pocket.

35. Unfortunately, the defect of the Cochlear Implants has disproportionately impacted children. At the time of publishing of the Reliability Report issued by Advanced Bionics in July 2024, Exhibit P-6, nearly 40% of both "V1" models of the Cochlear Implants in children had already been explanted.

36. As for adult patients, nearly 25% have required explants of the HiRes Ultra 3D "V1" Cochlear Implant, and nearly 30% have required explants of the HiRes Ultra "V1" Cochlear Implant.

37. Taking into account the mean time to detect a device failure, it is likely that the revision failure rate for the Defendants' two Cochlear Implant models will be greater than 50%.

38. Indeed, the "Cumulative Removal Percentage" for HiRes Ultra devices at Drs. Gärtner and Lenarz's clinic was 32.7% in adults and 59% in children, Exhibit P-9.

C. The defect in the Cochlear Implants causes serious injuries

39. The defect in the Cochlear implants has had profound consequences on patients.

40. As noted by Drs. Gärtner and Lenarz, if the failure of a cochlear implant occurs early, or even immediately after implantation, adult patients may not perceive any distortions or impairment in sound quality, as they have not yet had the opportunity to experience the full potential of the devices. This can lead the patient to living with a malfunctioning Cochlear Implant for extended periods of time.

41. Indeed, sophisticated audiological tests are required in order to determine whether a Cochlear Implant is defective. Crucially, as Drs. Gärtner and Lenarz note, the most important of these tests – EFI – cannot be conducted in a normal clinical setting since Advanced Bionics has not made the required software available to healthcare professionals.

42. A malfunctioning cochlear implant can often have serious impacts on patients' emotional, psychological and social well-being. For instance, a reduction in performance of the device can lead to increased difficulties in maintaining conversations and socializing, which in turn can lead to social isolation or depression.

43. For pediatric patients, the defective Cochlear Implants present unique challenges. As discussed above, at such a young age, the auditory cortex is still under development, and the failure of a cochlear implant may normalize impairment. Revision surgery is required immediately to minimize damage to the language development process.

44. Conversely, lack of auditory stimulation in children can cause delay or deviations in neural development that have long-lasting harmful effects on auditory development, language acquisition and cognitive abilities.

45. Similarly, for prelingual patients, unilateral auditory input can cause asymmetrical development of the auditory cortex, which can compromise the way that the auditory system responds to stimulation from a subsequent implant in the other ear.

46. In addition to risks related to hearing quality, the defect of the Cochlear Implants can cause loud noises in the inner ear, such as cracking or popping, as well as fever, pain or shocks throughout the face.

47. The defect can also cause vertigo, dizziness and convulsions as well as physical injuries related to these adverse effects, such as falls and motor vehicle accidents.

48. Patients whose implant fails also face the prospect of a second risky, invasive and time-consuming surgery, as detailed above. Indeed, Drs. Gärtner and Lenarz note that in their experience, adult patients hesitate to be reimplanted even when their speech comprehension has deteriorated. Risks and complications associated with revision surgery include:

    - Total hearing loss;
    - Bacterial meningitis (causing swelling of the brain and spine);
    - Tissue death;
    - Facial nerve damage;
    - Cerebrospinal fluid leakage;
    - Perilymph fluid leakage;
    - Skin wound infection;
    - Blood or fluid collection at the surgical site;
    - Dizziness or vertigo;
    - Tinnitus (ringing in the ears);
    - Sensory trouble (i.e., taste is affected);
    - Numbness around the ear; and
    - Inflammation and implant rejection.

49. As detailed above, patients who do proceed with revision surgery face a second long rehabilitation process to program their new cochlear implant. This process is associated to heightened stress due to the uncertainty surrounding the performance of the new implant. As with any invasive surgery, convalescence is often highly painful.

50. Further, all revision surgeries are associated with a higher risk of surgical failure. Indeed, implantation and removal of cochlear implants can cause structural damage to the inner ear complicating subsequent implantation.

51. Finally, many class members have suffered or will suffer loss of income. Their loved ones – who are also included in this class action - will suffer from this situation, in

addition to suffering from loss of companionship and degradation of relationships, as well as the need to devote increased time and energy to care for class members suffering from a defective Cochlear Implant.

D. The Cochlear Implants were based on a flawed concept and improperly tested

52. When seeking regulatory approval, Advanced Bionics presented the HiRes Ultra series of implants as a "repackaging" of commercially available devices that it had previously brought to market, namely the "HiRes 90K" and "HiRes 90K Advantage" (hereafter, the "**90K Implant**"). This "repackaging" involved, according to Advanced Bionics, incorporating the device "into new housing to reduce the size of the implanted components and to simplify the surgical procedure", as appears from a copy of the "Instructions for Use – HiResolution™ Bionic Ear System" distributed by Advanced Bionics in the United States, **Exhibit P-10**.

53. This was a highly risky decision, given that the 90K Implant had itself been subject to three distinct recalls, namely:

    a. In September 2004, all 90K Implants were recalled due to the potential presence of moisture in the internal circuitry, as appears from an entry in the FDA's database for medical devices dated September 27, 2004, **Exhibit P-11**. Patients, including children, suffered symptoms including sudden pain, loud noises, popping sounds and intermittent functioning. The 90K Implants were subsequently re-introduced to the market.

    b. In March 2006, certain 90K Implants were recalled again for elevated moisture levels, which could cause "intermittent function, complete loss of sound, sudden discomfort, pain, noise, or popping", as appears from an entry in the FDA database for medical devices dated March 8, 2006, **Exhibit P-12**. Advanced Bionics claimed that these problems were caused by a component in the device that was manufactured by a new and unauthorized supplier. In July 2008, Advanced Bionics paid a $1.1 million civil penalty to the FDA for its failure to notify the agency of this new supplier, as appears from an article published in *Medical Device and Diagnostic Industry* on July 18, 2008, **Exhibit P-13**.

    c. In November 2010, Advanced Bionics issued a full recall of all unimplanted HiRes 90K devices, after patients "experienced severe pain, overly loud sounds and/or shocking sensations" following the initial activation of the device, as appears from an entry in the FDA database dated November 23, 2010, **Exhibit P-14**. Certain 90K devices were again subsequently re-introduced into the market.

54. As can be seen, two of these recalls explicitly cited the exact same defect as that affecting the HiRes Ultra Cochlear Implants, namely excessive moisture in their components.

55. Despite the clear shortcomings of the 90K Implants, Advanced Bionics relied only on the clinical studies conducted on these devices or their components – or used in order to obtain regulatory approval for them – to obtain regulatory approval for the HiRes Ultra Cochlear Implants.

56. Indeed, as appears from the HiRes Ultra Instructions for Use, Exhibit P-10, the fact that the HiRes Ultra was a "repackaging" of the 90K device was used to justify the fact that no clinical studies whatsoever were conducted on the HiRes Ultra Cochlear Implants before their introduction to the market.

57. Advanced Bionics did this despite the fact that the studied 90K Implants were implanted with different models of electrodes – namely the "HiFocus" and the "HiFocus Helix" – whereas the HiRes Ultra Cochlear Implants were implanted with newly developed models, the "HiFocus SlimJ" and the "HiFocus Mid-Scala" electrodes.

58. Finally, the 90K Implant itself was not even the subject of a clinical trial, whereby special status is granted to a device in order to allow its implantation in a select group of participants in a pre-market study. Instead, Advanced Bionics relied on the clinical trials conducted for previously marketed devices (hereafter, the "**Clarion**" and "**Clarion CII**", the "**Clarion Implant**") in order to obtain authorization to bring the 90K Implant to market.

59. It is noteworthy that a significant number of patients (5 out of 80, or 6,3%) who took part in the Clarion Implant clinical trial had reported vestibular symptoms, namely dizziness and/or spinning sensations.

E. Advanced Bionics wrongfully delayed its recall of the Cochlear Implants

60. In their article, Drs. Gärtner and Lenarz noted that a new pattern of anomalies, specific to the defect in the Cochlear Implant, was first detected in April 2019.

61. However, given the periods of implantation of the devices, as well as observed periods for the first appearances of anomalies, it is certain that cases highly indicative of device failure were observed by Drs. Gärtner and Lenarz well before April 2019.

62. Given that Drs. Gärtner and Lenarz were conducting a clinical study for Advanced Bionics and that the latter was on-site at their clinic, Advanced Bionics was informed of all instances of possible device failures.

63. Despite being made aware that the Cochlear Implants were defective, Advanced Bionics chose to leave these devices on the market while they developed new, supposedly non-defective versions of the devices.

64. As Advanced Bionics stated in an "update", **Exhibit P-15**, on the recall of the Cochlear Implants published on October 31, 2022:

> *In response to early indications of the original Ultra / Ultra 3D implant performance issue, AB made device improvements to protect against fluid impacting the electrode.*
>
> [emphasis added]

65. In June 2019 at the latest, Advanced Bionics undertook steps to obtain regulatory approval from the FDA of the new, "Version 2" of the Cochlear Implants, as appears from an excerpt of the FDA's database for medical devices, **Exhibit P-16**.

66. The FDA approved the "V2" models on December 23, 2019, as appears from an excerpt of the FDA's database for medical devices, **Exhibit P-17**.

67. Nevertheless, Advanced Bionics continued to market and sell the defective "V1" Cochlear Implants until February 2020, whereupon it finally issued a recall of the devices as detailed above.

68. Even when it did issue this recall, Advanced Bionics downplayed the risks of the Cochlear Implants, maintaining that the performance was observed in "a limited number" of devices, that the recall was being made with "an abundance of caution" and that the "situation does not present a device-related safety issue", as appears in the Advanced Bionics media release dated February 18, 2020, **Exhibit P-18**.

F. The Liability of the Defendants

69. As appears from the above, the Cochlear Implants contain a safety defect. The Defendants are thus liable to repair the injuries caused to class members by this safety defect pursuant to art. 1468 of the *Civil Code of Québec*[2] (*CCQ*).

70. Furthermore, and as detailed above, the Defendants marketed a medical device that is crucial to the health and well-being of class members despite knowing that this device presented unreasonable risks. In so doing, the Defendants acted with callous disregard for the safety and well-being of class members with a view to maximizing their profits. More specifically, the Defendants:

    a. Brought the Cochlear Implants to market despite the fact that their predecessor devices had been recalled for numerous and identical defects;

    b. Conducted insufficient studies in order to adequately determine whether the Cochlear Implants were safe and effective, particularly in light of the failings of their predecessor devices;

    c. Failed to warn healthcare professionals and patients of the risks of failure and physical harm posed by the Cochlear Implants, namely by reason of

[2] S.Q. 1991, c. 64.

the defects of their predecessor devices and the insufficient studies conducted upon them;

d. Failed to immediately remove the Cochlear Implants from the market, and failed to immediately notify healthcare professionals, patients and public health authorities, upon receiving confirmation that the Cochlear Implants were defective.

71. This conduct constitutes an illicit and intentional violation of class members' right to personal security protected by the *Charter of Human Rights and Freedoms*.[3] The Defendants are thus liable to pay compensatory and punitive damages to class members pursuant to art. 49 of said *Charter*.

G. The Failure of the Plaintiff's Cochlear Implant

72. The Plaintiff served in the Canadian Armed Forces in Germany. He lost his hearing due to prolonged proximity to outgoing machine gun fire.

73. As mentioned, the Plaintiff was implanted with a Cochlear Implant on his left side at the CHU de Québec – Université Laval in Québec City in 2017, as appears from a copy of the operative report and the "fiche d'implantation", **Exhibit P-19** *en liasse* (under seal). He wears a hearing aid on his right side meant to complement the Cochlear Implant through a Bluetooth connection.

74. The Plaintiff experienced severe pain at the incision site during his recovery from his implant surgery.

75. The activation and programming portion of his recovery was frustrating and highly stressful. The Plaintiff frequently could not understand what was being asked of him by healthcare professionals. He felt fear at the prospect of recovering only limited hearing.

76. After the surgery, the Plaintiff noticed that his hearing had partially improved: it was better in some areas, but not in others. Not knowing what to expect and not having a benchmark for how well a cochlear implant was supposed to work, he assumed that this level of improvement was normal.

77. However, after a while, the Plaintiff noticed problems with his hearing. For instance, at the church he attended in Rivière-Rouge, he noticed that it was very difficult for him to maintain a conversation in a room with background noise.

78. The Plaintiff moved to Golden Lake, Ontario in December 2020, then to London, Ontario in early 2022.

79. Beginning in early 2021, the Plaintiff noticed severe degradation of the performance of his Cochlear Implant: he now found it very difficult to distinguish between different sounds, and some sounds appeared to him as shrill for no reason. It was also

[3] CQLR c C-12.

exceedingly difficult for him to maintain conversations in any location with background noise.

80. The Plaintiff is an extremely social person. He is a pastor and a counselor at his local legion. When his Cochlear Implant began to fail, he lost his ability to socialize and found this extremely distressing. His poor hearing led to frequent miscommunications with people seeking his counselling, which he found embarrassing and frustrating.

81. He also had great difficulty communicating with his loved ones. For instance, he found it very difficult to understand his son – who lives in Shefford, Québec – over the phone.

82. In addition to the decline in his hearing, the Plaintiff experienced many vestibular symptoms such as loss of balance, vertigo and dizziness. These symptoms were particularly pronounced immediately following the implant surgery, but he continued to experience them on a regular basis in the long-term. On one occasion, they led him to fall off his toilet and crash through the door of his shower. He suffered many cuts as a result.

83. As appears from his audiology records at the London Health Sciences Center, **Exhibit P-20** (under seal), testing of the Plaintiff's Cochlear Implant by both his treating audiologist, Laura Hopkins, and representatives of Advanced Bionics revealed the implant had failed due to fluid ingress.

84. Ms. Hopkins thus informed the Plaintiff that revision surgery would be required for him to recover his hearing.

85. The Plaintiff was extremely reluctant to undergo revision surgery of his Cochlear Implant as he did not want to experience the painful, frustrating and fear-inducing rehabilitation process for a second time. He was also worried about the risks of revision surgery associated with his age.

86. However, faced with consistent decline in his hearing, the Plaintiff ultimately underwent the revision surgery on October 8th, 2024 at the Ottawa Hospital, as appears from the operative note, **Exhibit P-21** (under seal).

87. The Plaintiff has experienced a noticeable improvement in his hearing since the revision surgery: he is overall better able to communicate with others and engage in activities such as watching television, which has significantly improved his quality of life.

88. However, his hearing has not reached the same level as after the first implant surgery: for instance, he still finds it difficult to communicate over the phone or use headphones.

WHEREFORE MAY IT PLEASE THIS HONOURABLE COURT:

GRANT the class action against the Defendants;

ORDER, the Defendants, solidarily, to pay class members an amount to be determined by the Court in compensation of their bodily, moral and material injuries;

ORDER collective recovery of the non-pecuniary damages due to class members;

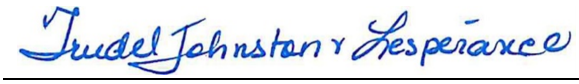
ORDER individual recovery of the pecuniary damages due to class members;

ORDER the Defendants to pay punitive damages in the amount of $5,000,000.00 (five million dollars);

ORDER collective recovery of punitive damages;

THE WHOLE with interest, legal indemnity and costs, including but not limited to expert fees, notice dees and fees relating to administration of recovery.

MONTREAL, August 25th, 2025



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TORONTO, August 25th, 2025

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TORONTO, August 25th, 2025

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Co-counsel for Plaintiff

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SUMMONS
(Art. 145 ss. *C.C.P.*)

Filing of a judicial application

Take notice that the Plaintiff has filed this originating application in the office of the Superior Court in the judicial district of Montreal.

Defendant's answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal, situated at 1 Notre-Dame Street East, H2Y 1B6, within 15 days of service of this application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the Plaintiff's lawyer or, if the Plaintiff is not represented, to the Plaintiff.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgment may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- Negotiate a settlement;
- Propose mediation to resolve the dispute;
- defend the application according to the rules set out in Title I.1 of Book VI of the Code of Civil Procedure (articles 535.1 to 535.15), in particular, by filing with the court office a brief outline of your arguments within 95 days after service of this summons; or;
- Propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Where to file the judicial application

Unless otherwise provided, the judicial application is heard in the judicial district where your domicile is located, or failing that, where your residence or the domicile you elected or agreed to with Plaintiff is located. If it was not filed in the district where it can be heard and you want it to be transferred there, you may file an application to that effect with the court.

However, if the application pertains to an employment, consumer or insurance contract or to the exercise of a hypothecary right on the immovable serving as your main

residence, it is heard in the district where the employee's, consumer's or insured's domicile or residence is located, whether that person is the Plaintiff or the defendant, in the district where the immovable is located or, in the case of property insurance, in the district where the loss occurred. If it was not filed in the district where it can be heard and you want it to be transferred there, you may file an application to that effect with the special clerk of that district and no contrary agreement may be urged against you.

Transfer of the application to the Small Claims Division

If you qualify to act as a Plaintiff under the rules governing the recovery of small claims, you may contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the Plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Convening a case management conference

Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing that, the protocol is presumed to be accepted.

Exhibits supporting the application

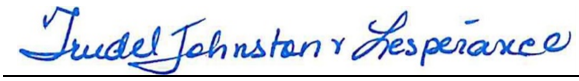
In support of the originating application, the Plaintiff intends to submit the exhibits enumerated in the attached *Plaintiff's List of Exhibits*.

These exhibits are available upon request.

Application accompanied by a notice of presentation

Applications filed in the course of a proceeding and applications under Book III or V of the Code of Civil Procedure—excluding applications pertaining to family matters under article 409 and applications pertaining to securities under article 480—as well as certain applications under Book VI of the Code of Civil Procedure, including applications for judicial review, must be accompanied by a notice of presentation, not by a summons. In such circumstances, the establishment of a case protocol is not required.

MONTREAL, August 25th, 2025



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Our file: 1490-1

TORONTO, August 25th, 2025

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C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF **MONTREAL**

No.: 500-06-001254-230

(Class Actions)
S U P E R I O R C O U R T

HERBERT "TROY" DINGWELL

Plaintiff

v.

ADVANCED BIONICS L.L.C.

and

ADVANCED BIONICS AG

and

SONOVA HOLDING AG

and

SONOVA AG

and

SONOVA CANADA INC.

Defendants

and

RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC

and

ATTORNEY GENERAL OF QUEBEC

Interveners

PLAINTIFF'S LIST OF EXHIBITS

Exhibit P-1: Excerpts from the Sonova Group's Annual Report, 2024-2025

Exhibit P-2: Information sheet on the *Registre des entreprises* for Sonova Canada Inc.

Exhibit P-3: Excerpts from the Sonova Groups Annual Report for 2016-17

Exhibit P-4: Press release issued on Business Wire by Advanced Bionics on February 20, 2017

Exhibit P-5: Press release issued on Business Wire by Advanced Bionics on April 8, 2019

Exhibit P-6: Advanced Bionics Reliability Report, July 2024

Exhibit P-7: Entry in the United States Food and Drug Administration's ("FDA") database for medical devices regarding the recall of the HiRes Ultra Cochlear Implants dated February 17, 2020

Exhibit P-8: Medical Device Recall for the HiRes Ultra Cochlear Implants published by Health Canada on April 17, 2020

Exhibit P-9: Journal article entitled "Advanced Bionics HiRes Ultra and Ultra 3D Series Cochlear Implant Recall: Time Course of Anomalies" by Dr. Lutz Gärtner and Dr. Thomas Lenarz published in the *The Laryngoscope* in December 2022

Exhibit P-10: "Instructions for Use – HiResolution™ Bionic Ear System" distributed by Advanced Bionics in the United States

Exhibit P-11: Entry in the FDA's database for medical devices regarding the recall of the 90K HiRes Cochlear Implants dated September 27, 2004

Exhibit P-12: Entry in the FDA's database for medical devices regarding the recall of the 90K HiRes Cochlear Implants dated March 8, 2006

Exhibit P-13: Article published in *Medical Device and Diagnostic Industry* on July 18, 2008

Exhibit P-14: Entry in the FDA's database for medical devices regarding the recall of the 90K HiRes Cochlear Implants dated November 23, 2010, also available at the following link: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=95924

Exhibit P-15: Advanced Bionics Update on the Recall of the HiRes Ultra Cochlear Implants dated October 31, 2022

Exhibit P-16: Entry in the FDA's database for medical devices regarding the pre-market approval of V2 of the Cochlear Implants dated July 3, 2019

Exhibit P-17: Entry in the FDA's database for medical devices regarding the pre-market approval of V2 of the Cochlear Implants dated December 23, 2019

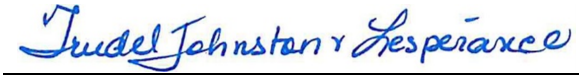
Exhibit P-18: Advanced Bionics media release regarding the recall of the Cochlear Implants, February 18, 2020

Exhibit P-19: Operative report for initial implantation surgery dated December 15, 2017 (under seal)

Exhibit P-20: Claimant audiology records from the London Health Sciences Centre (under seal)

Exhibit P-21: Operative report for revision surgery dated October 8, 2024 (under seal)

MONTREAL, August 25th, 2025



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No.: 500-06-001254-230

S U P E R I O R C O U R T
DISTRICT OF **MONTREAL**
(Class Actions)

HERBERT "TROY" DINGWELL

Plaintiff

v.

ADVANCED BIONICS LLC et al.

Defendants

and

RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC et al.

Interveners

ORIGINATING APPLICATION IN A CLASS ACTION

ORIGINAL

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