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23 SUPERIOR COURT OF THE STATE OF CALIFORNIA
 24 FOR THE COUNTY OF LOS ANGELES
 25 CENTRAL CIVIL WEST COURTHOUSE

26 RICHARD THOMAS and ROSALIE THOMAS,)
 27 his wife,)

28 Plaintiffs,)

v.)

29 ADVANCED BIONICS CORPORATION, a)
 30 California Corporation, ADVANCED)
 31 BIONICS, LLC, a Delaware Limited Liability)
 32 Company, ASTRO SEAL CORPORATION, a)
 33 California Corporation, and DOES 1 through 50)
 34 Inclusive,)

35 Defendants.)

No. _____

BC429170

**COMPLAINT FOR (1) NEGLIGENCE
 PER SE; (2) NEGLIGENCE PER SE;
 (3) STRICT LIABILITY; (4) FAILURE
 TO WARN; (5) BREACH OF EXPRESS
 WARRANTIES; (6) BREACH OF
 IMPLIED WARRANTIES;
 (7) COMMON LAW FRAUD;
 (8) CALIFORNIA CONSUMERS LEGAL
 REMEDIES ACT; (9) CALIFORNIA
 UNFAIR UNCOMPETITION LAW;
 AND (10) IOWA CONSUMER FRAUD
 ACT**

DEMAND FOR JURY TRIAL

Dep't: 309 [Hon. Anthony J. Mohr]

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 OF ORIGINAL FILED
 Superior Court of California
 County of Los Angeles

JAN 04 2010

John A. Clarke, Executive Officer/Clerk
 By RUGENA LOPEZ, Deputy

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FIRST CAUSE OF ACTION NEGLIGENCE PER SE (Violation of Federal Law) (Against Advanced Bionics, Astro Seal and Does 1 through 10) 26

SECOND CAUSE OF ACTION NEGLIGENCE PER SE (Violation of State Law) (Against Advanced Bionics, Astro Seal and Does 11 through 15) 29

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1 Richard Thomas and wife Rosalie Thomas hereby sue Defendants Advanced Bionics
2 Corporation, Advanced Bionics, LLC, Astro Seal, Inc. and Does 1-50, for damages, and
3 respectfully allege in support thereof as follows:

4 **I. PARTIES**

5 1. Plaintiff Richard Thomas was born December 12, 1950, making him fifty-nine (59)
6 years old as of the filing of this lawsuit. At all times material to this lawsuit, Richard Thomas has
7 resided in Davenport, Iowa. Mr. Thomas had been deaf in his left ear since childhood and in his
8 right ear since the week of May 17, 2004.

9 2. Plaintiff Rosalie Thomas is the wife of Richard Thomas, is over the age of 18, and
10 resides with her husband in Davenport, Iowa.

11 3. Advanced Bionics Corporation is a California Corporation, with its principal place
12 of business in Sylmar, California.

13 4. On February 1, 2005, the FDA took further action against Advanced Bionics'
14 cochlear implant business, issuing a "Warning Letter" in which the FDA reported that as a result of
15 the August 25 through September 15, 2004 inspection, the FDA had determined that "[Advanced
16 Bionics'] devices were adulterated within the meaning of section 501(h) of the [Federal Food,
17 Drug, and Cosmetic] Act."

18 5. Advanced Bionics is in the business of manufacturing cochlear implant devices.

19 6. Astro Seal, Inc. (also referred to as "AstroSeal") is a California corporation, with its
20 principal place of business in Riverside, California. Advanced Bionics hired Astro Seal to
21 manufacture an important component part of its cochlear implant device known as a feedthru (or
22 feed-through) assembly. Astro Seal manufactured and supplied the feedthru assemblies used in
23 certain Advanced Bionics' cochlear implant devices. The feedthru is the part that conducts
24 electrical signals from the hermetically (waterproof) sealed implanted part to the electrode array.

25 7. The true names and capacities of the defendants sued herein as Does 1 through 50,
26 inclusive, are unknown to Plaintiffs, and are therefore sued under such fictitious names. Plaintiffs
27 will amend this Complaint to allege the true names and capacities of Does 1 through 50, if and
28

1 when ascertained. Plaintiffs allege on information and belief that said fictitiously named
2 defendants are in some manner responsible, in whole or in part, for the matters alleged herein.

3 4 **II. FACTUAL BACKGROUND**

5 **A. Cochlear Implants**

6 8. A cochlear implant is a Class III medical prosthesis designed to enable profoundly
7 deaf persons to “hear” by directly stimulating auditory nerves leading to the brain by means of an
8 electrode array strategically positioned in the cochlea of the inner ear.

9 9. Unlike hearing aids, cochlear implants do not amplify sound. Instead a miniature
10 computer/sound processor, worn outside the body, selectively processes sound into coded signals.
11 Such signals are transmitted by wireless electromagnetic conduction to an implantable cochlear
12 stimulator (ICS) that is surgically implanted in the patient’s body.

13 10. The ICS receives these coded signals and interprets them using its sophisticated
14 microelectronic architecture to send specialized patterns of electrical current to the electrodes
15 inserted inside of the cochlea. Multiple electrodes along the length of the electrode array emit
16 electrical currents in the form of electrical stimulation pulses to the surrounding hearing nerve
17 receptors based on scientific knowledge that different parts of the cochlear are sensitive to different
18 sound frequencies. Nerve fibers then send this information to the brain for central processing,
19 interpretation, and perception as sound.

20 11. Cochlear implant surgery requires general anesthesia and often involves a procedure
21 called a mastoidectomy, in which an incision is cut and an indent is drilled into the skull to allow
22 the attachment of the implant. Once the implant is attached, the electrode array is inserted in the
23 delicate coiled cochlea of the inner ear by making a hole called a cochleostomy and inserting the
24 electrode array and pushing it through as gently as possible to avoid trauma to the inner surfaces.
25 Post-surgery vertigo and nausea are common. Paralysis of the facial nerves is a rare but possible
26 risk of surgery, as is tinnitus and damage to the vestibular system.

27 12. After surgery, initial programming of the external processor is not done until the
28 incision has healed, which typically takes two to five weeks. At such initial stimulation and

1 programming, the individual electrodes are programmed at appropriate threshold and amplitude
2 levels based on the patient's response to stimulation which is then used to create an electrode
3 "map." Once all of the electrodes are mapped, the processor is turned on and the cochlear implant
4 patient can "hear." This programming process continues to be fine-tuned at later appointments
5 throughout the first year with the external processor eventually being programmed with multiple
6 maps for different auditory environments.

7 13. In normal hearing, the cochlea is stimulated by hundreds of thousands of hair cells.
8 The stimulation of the cochlea through implanted electrodes is very different. Thus a cochlear
9 implant demands a long rehabilitation period in which the cochlear implant recipient's brain must
10 learn how to decode and recognize sound.

11 14. The perception of sound by cochlear implant users is very different from normal
12 hearing. Cochlear implant patients who have lost their hearing often describe the initial stimulation
13 as hearing tinny "buzzes" and "whistles" that had no relation to what they remembered as sound
14 and felt that they would never be able to comprehend.

15 15. Gradually through aural rehabilitation and listening experience, the brain may learn
16 to decode sound. Over time, some cochlear implant recipients learn to distinguish sounds well
17 enough so that they can talk on the telephone through the cochlear implant or listen to TV without
18 closed-captioning.

19 16. When a defective cochlear implant is replaced, the electrode array may not be re-
20 implanted in the same position in the cochlea, leading to different threshold and amplitude settings.
21 As a result, rather than starting off by "hearing" at the comprehension level where the defective
22 implant failed, a cochlear implant patient may have to go through a second aural rehabilitation
23 before the replacement implant functions at the same level as the first implant did.

24 17. There is no guarantee that a replacement cochlear implant will ever function at the
25 same level as the first. In some cases, due to cochlea scarring or nerve damage from explant
26 surgery, different electrode positioning, or other causes, a cochlear implant patient may not
27 function as well with the replacement implant.

1 18. Different cochlear implant manufacturers use different sound strategies. Thus when
2 a defective implant is replaced with a new device by a different cochlear implant manufacturer, an
3 entire new sound system needs to be learned.

4 19. Bilateral implantation, in which cochlear implants are surgically implanted in both
5 ears, is increasingly becoming a desirable option for young children based on recent clinical
6 research findings. The reasoning is that bilateral sound assures that sound is processed through
7 both sides of the brain, which enables the brain to mature and to learn to process bilateral
8 information during a period where maximum brain plasticity and linguistic development occurs.

9 **B. Mr. Thomas' Experience with an Advanced Bionics' Cochlear Implant**

10 20. On or about August 9, 2004 Plaintiff Richard Thomas was implanted with an
11 Advanced Bionics HiRes 90k cochlear implant, serial number 221888, manufactured on May 28,
12 2004, behind his right ear at the University of Iowa Medical Center.

13 21. Advanced Bionics did not inform Mr. Thomas prior to being implanted with his
14 HiRes90k cochlear implant that there were problems with other Advanced Bionics cochlear
15 implants failing for moisture-related concerns, including with the C1.2 cochlear implant, the CII
16 cochlear implant and the HiRes 90k cochlear implant.

17 22. Astro Seal supplied Advanced Bionics with the feedthru component for the
18 HiRes90k that was implanted during Mr. Thomas' surgery on August 9, 2004.

19 23. In January 2009, Mr. Thomas experienced intermittent sound with his cochlear
20 implant. He proceeded to the University of Iowa for treatment in February 2009 after replacing
21 external parts during January 2009 thinking that the problem was an equipment issue.

22 24. Mr. Thomas was frustrated as a result of the malfunction with his implant.

23 25. Mr. Thomas would at times have to lower/adjust the volume in the device once it
24 began to fail, and at times Mr. Thomas would turn the device off altogether because of difficulties
25 with discomfort and hearing.

26 26. Mr. Thomas went to the University of Iowa on or about February 26, 2009 for
27 assistance with his Advanced Bionics cochlear implant. Mr. Thomas' external hardware was
28

