I. Manufacturer

Manufacturer: Advanced Bionics, LLC
12740 San Fernando Rd.
Sylmar, California 91342
Establishment Number: 300655611

Contact: Cedric Navarro
Vice-President, Regulatory Affairs
Tel: (661) 362-1963
Fax: (661) 362-7621
Cell: (661) 993-3878
E-Mail: cedricn@bionics.com

II. Identities of Product

This voluntary Field Action is for all unimplanted HiRes 90K cochlear implants (model numbers are CI-1400-01 and CI-1400-02H). This field action affects all unimplanted HiRes 90K devices manufactured since July 2008. This date is based on a two year sterile shelf life of the HiRes 90K device with a three month margin added.

III. Intended Use of the Device

The Harmony HiResolution® Bionic Ear system is a cochlear implant system designed to provide useful hearing to individuals with severe-to-profound sensorineural hearing loss. The cochlear implant system consists of internal and external components. The internal components include a receiver (the HiRes 90K), and electrode array (HiFocus 1J or HiFocus Helix) that are implanted surgically under the skin behind the ear. The electrode array is inserted into the cochlea. The HiRes 90K receiver includes a telemetry coil, magnet and electronics. The electronics are contained within a hermetically sealed titanium case. The external components include a sound processor (body worn or ear-level), a cable and a headpiece. The system converts sound into electrical energy that activates the auditory nerve. The auditory nerve then sends information to the brain, where it is interpreted as sound.

IV. Reason for Removal and Event History

This removal is being initiated to address the issue of a short in a component of the HiRes 90K device HR90K. This component, the substrate, is a part of the hybrid subassembly (See Figure 1). Advanced Bionics has become aware of a potential failure mechanism which could result in the type of substrate short seen in two explants (SN 325079 and SN 327755). In both cases, the patient was temporarily exposed to DC leakage. It is known that exposure to very high levels of DC leakage can cause permanent damage to neural tissue if the patient is subjected to a high current level for a prolonged time.

To date, out of 28,000 implanted patients, this latent short has only occurred in two patients who were explanted. Both patients have been re-implanted with HiRes 90K devices and their clinicians report that they are progressing well. There is no evidence to suggest that the patients suffered any permanent damage as a result of this issue.

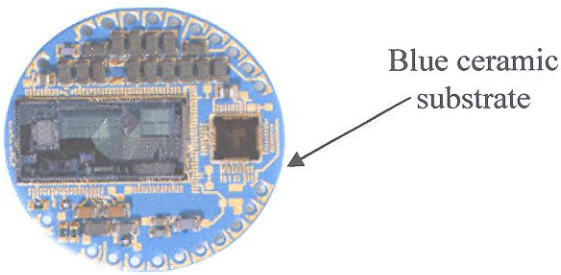

Figure 1: HiRes 90K hybrid assembly

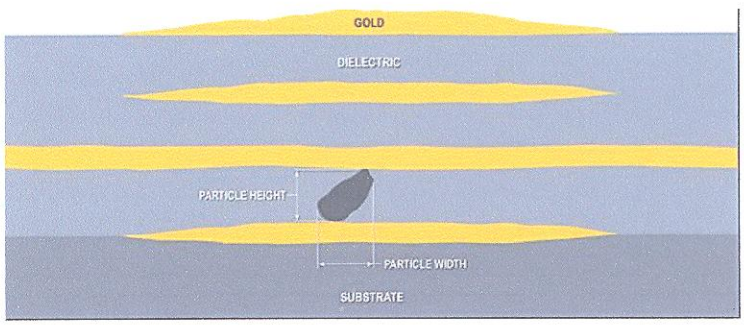

Figure 2: Latent particle short between substrate layers

The latent short in the substrate is believed to be due to a short in the dielectric layer that separates the device power supply from the outputs to the electrode. This short did not exist at the time the substrate was manufactured, nor did it exist at the time the device was tested at Advanced Bionics prior to shipment. The short occurred at a location in the dielectric which is between two metal layers (See Figure 2). The dielectric in this location is believed to have been bridged by a large particle. At the time this substrate was manufactured, this particle was not conductive and therefore the short did not exist. However, after the device was implanted and

energized the electrical properties of this particle began to change. Over the course of 8 -10 days, this large particle became conductive. At that time, this large particle formed a bridge that allowed current from the power supply to short directly to an electrode. This resulted in DC current being sent to the patients' cochlea. The suspected large particle that caused this issue is not a contaminant, but rather a known ingredient of the dielectric material.

As part of our investigation into this failure mode, we have hired an independent scientific research organization. Their latest analysis suggests that, if the potential for a latent short to develop exists in a device, it will first occur within 90 days of device use. It is for this reason that the affected patient population has been identified to be all patients implanted less than 120 days. This decision and the associated rationale is documented in Product Inquiry Report, PIR0010 (See Appendix A).

V. Health Hazard Evaluation

Advanced Bionics has completed its assessment of the health hazard presented by this issue. We have decided that a voluntary recall of all unimplanted HiRes 90K cochlear implants is required to avoid the remote chance of patient harm.

Latent shorts in the substrate can cause high levels of DC current that result in overly loud and painful stimulation. In the case where the patient is subjected to these high levels of DC current for a long period of time, neural tissue can be damaged. In the event that this issue occurs, there are two levels of harm which may result:

1. The patient will receive a very loud and painful stimulation. If they remove their headpiece and thus remove power from their implant, this stimulation will stop.
2. If the patient is unable to remove their headpiece, or they continue to be stimulated for a prolonged period of time, then they run the risk of permanent neural tissue damage.

While, the most serious injury that can occur is neural tissue damage due to DC current. It is important to note that there are no confirmed cases where this has occurred. In order for this serious injury to occur, there would first have to be a device that exhibited a substrate short resulting in DC current sent to the electrode AND then the patient would have to be subjected to this for a sufficiently long period of time by not removing their headpiece. To date, we have only confirmed two devices with DC leakage due to this issue out of an implanted based of 28,000 devices. In both cases, the patient quickly removed the headpiece and limited the duration of exposure to the DC leakage. We have assigned the probability of a patient not removing their headpiece in the presence of DC current as one in twenty. We therefore have estimated the probability of the most serious injury as: (2/28,000)*(1/20) = 1/280,000. According to our scale for assigning probabilities this is a remote occurrence.

The population that is at greatest risk for this issue are patients that cannot remove their headpieces when they are exposed to overly loud and painful stimulation. This includes very young children and others who are not physically capable of removing their headpiece. It is for this reason that in addition to recalling all unimplanted product, Advanced Bionics is requiring all patients who have implanted with a HiRes 90K device for less than 120 days to be notified, as well as, all clinicians and surgeons.

VI. Notification Strategy

Advanced Bionics has created three notification letters which shall be delivered:

- Patient letter for those patients who have been implanted less than 120 days
- Surgeon letter
- Clinician letter

Each letter includes an acknowledgement form for each recipient to sign as proof that the notification has been read. The Company will use the forms to verify the effectiveness level of the notification.