



Missouri Department of Health and Senior Services Recall Alert

The Missouri Department of Health and Senior Services has received this recall from the FDA regarding a certain type of cochlear implant. Please see below for further details.

Device will be Recalled from the Market while the Company Works with the US Food & Drug Administration to Address the Issue

Company Contact:

Ms. Cheryl Garma,
(661) 362-1400
mediaquestions@advancedbionics.com

FOR IMMEDIATE RELEASE – Valencia, CA, November 23, 2010 – Advanced Bionics (AB), a global leader in developing advanced cochlear implant systems, announced today that it has notified the US Food & Drug Administration (FDA) that it will voluntarily recall its HiRes 90K cochlear implant device and is retrieving all unimplanted devices in distribution. This action is being taken in response to two confirmed instances where the product experienced a malfunction requiring explantation. These recipients experienced severe pain, overly loud sounds and/or shocking sensations at 8-10 days after initial activation of their device.

AB is continuing to evaluate the root cause(s) of the problem and is working closely with the FDA to address their questions and concerns, and institute changes to the product to ensure that the HiRes 90K has the highest quality for patients who use the device. This voluntary action is being taken to ensure continued patient safety and product quality. The risk of any significant adverse medical events appears to be remote at present.

About Advanced Bionics

AB is a global leader in developing one of the most advanced cochlear implant systems in the world. Founded in 1993 and partnered with Phonak under the Sonova Group in 2009, AB develops cutting-edge cochlear implant technology that restores hearing to the deaf.

With sales in over 50 countries, AB's talented group of technologists and professionals from all over the world are driven to succeed, work with integrity, and stay firmly committed to quality.

###