POST- MARKETING EVALUATION FOR PERFORMANCE OF HIRES ULTRA 3D COCHLEAR IMPLANT

Study Category:

☑ Post-market evaluation study (دراسة تقييم سريري)

☐ Risk analysis report (تقرير تحليل مخاطر)

BACKGROUND
Cochlear implants are designed to help severely to profoundly deaf adults and children who get little or no benefit from hearing aids. They bypass the ear's normal sound conducting mechanism to stimulate the acoustic nerve directly. The device consists of an external microphone that captures sound and relays it to a processor, which then sends it to a transmitter that communicates wirelessly with a receiver under the skin. The receiver then converts the sound into electrical impulses that are carried by an electrode array that is surgically placed adjacent to auditory nerve fibers within the cochlea. The signal is transmitted within the central auditory system, which generally remains intact in deaf patients, to the auditory cortex, allowing patients to hear. This study evaluated the performance of HiRes Ultra 3D cochlear implant manufactured by Advance Bionics. Two electrode models were considered, which are HiFocus Mid-Scala (CI-1601-04), and HiFocus SlimJ (CI-1601-05).

CLINICAL BURDEN
The ear is responsible for collecting sounds and transmitting them to the brain for interpretation. This process involves three separate areas of the ear: the outer, middle, and inner ear. Hearing loss occurs when there is abnormality or damage to any of these parts. For most individuals, the problem occurs in the inner ear (or cochlea) where sound is transferred to the hearing nerve. In cases where the amplification provided by hearing aids is not enough, a cochlear implant is the standard treatment.

RISKS AND COMPLICATION

In February 2020, a manufacturer of a cochlear implant (Advanced Bionics) Issued FSCA regarding a specific lot number range of their device model (HiRes Ultra 3D). The reason of the FSCA was due to detection of an increased number of HiRes Ultra 3D explant, or the potential to be explanted as a result of a performance issue resulted in hearing performance degradation.

EVALUATION OUTCOMES

The evaluation was done by analyzing the data from NCMDR database where the adverse events are reported from the hospitals, and searching for incidents related to the device under investigation. In addition, a survey was sent to the cochlear implant surgeons, ENT consultants and phonologists in charge of following up cochlear implant patients at the hospitals where the device was distributed to generate a data of the device explant rate.

Analyzing the data from both NCMDR and the survey indicated that there are no any explant for any HiRes™ Ultra 3D due to a performance degradation, which make the explant rate in local healthcare providers to be less than the global rate of 0.5%.

SFDA ACTIONS

The results demonstrate that there is no action to be taken other than manufacturer's field corrective action to remove the affected version of the HiRes™ Ultra 3D product from circulation.

SFDA RECOMMENDATIONS

In regard to the percentage of explant of HiRes™ Ultra 3D due to a performance degradation among local healthcare providers, the data shows that the action taken by the manufacturer is enough to resolve the issue and no more regulatory action is needed other than following up with the local Authorized Representative to perform the corrective action. In the meanwhile, the healthcare practitioners are encouraged to report any adverse event related to this device.

ACKNOWLEDGMENT

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