Health Technology Review	
Technology Ref.:	HTA-23043
Technology Name:	Cochlear Implant System-Version1
Approvals by International Bodies:	ISO13085:2016.
Company name:	CE Mark South Korea.
Agent in UAE:	FDA- Philippines.
Email:	CDSCO.

Short Description of the Technology:	The BOLD Cochlear Implant System is designed to address severe to profound hearing loss, providing a breakthrough in auditory assistance. The system comprises two main components: • Internal Receiving Unit (IRU): Surgically implanted, this sterile device serves as the internal receiver, positioned within the ear. • Sound Processing Unit (SPU): This external hardware incorporates a sound processor and rechargeable battery pack. The processor captures external sounds through a microphone, transforms them into electrical signals, and transmits the processed output to the IRU through the skin.The IRU beneath the skin consists of a receiver coil for sound signal reception and electrodes for transmitting these signals to the auditory system.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Neubio's cochlear implant stands out as a groundbreaking technological differentiator in the market. The absence of electronics within the implant is a pivotal advancement, especially for pediatric recipients, as it ensures a lifetime free from the risks associated with electronic failures.
Neubio Cochlear Implant System offers a practical and advanced solution, bringing substantial advantages over conventional implants in the management of severe to profound hearing loss.

Advantages	Disadvantages
Neubio's implant distinguishes itself by incorporating no internal electronics. This innovative design significantly enhances safety, minimizing the risk of electronic failure within the implant.	Can cause meningitis, facial paralysis, wound infection, tinnitus, explantation, and temporary dizziness.
The absence of internal electronics allows for a smaller implant size, providing greater	Long-term effects of chronic electrical stimulation remain unknown, although

flexibility in surgical procedures.	clinical experience has shown no adverse effects.
The trans-canal approach, made possible by Neubio's implant design, offers the potential for surgeries that require less extensive anesthesia.	While the construction of the Bold CI electrode inserted in the cochlea is designed to minimize the likelihood of residual hearing loss, it cannot be guaranteed.
Neubio's Cochlear Implant System incorporates universal components, such as a charging port compatible with widely available standards like USB Type-C.	Diagnostic ultrasound energy should not be applied to the implant area.
	Direct impact to the implant site may damage the devic.

We recommend an **approval this technology** with the following conditions:

1. 1. Cochlear Implant System/ BOLD I should be performed by (ENT) specializes.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

technology Image

Bold I

Population, setting and intended user for Technology “”

- **Population/ Intended User**;
  - Bilateral profound sensorineural hearing loss
  - Limited benefit from amplification/hearing aid.
- **To be performed by**:
  - By Ear, Nose, and Throat doctor (ENT) specializes.
- **Clinical Setting:**
  - Hospitals, special ENT surgery centers
- **Condition of use:**
  - The BOLD Cochlear Implant System aims to restore a sensation of hearing in individuals aged 12 months and older.
- **Exclusion criteria:**
  - The BOLD CI system is contraindicated for individuals with conditions such as deafness.
  - middle ear infections.
  - cochlear ossification preventing electrode insertion.
  - absence of cochlea.