FDA 510(k) Premarket Notification

CLEARED

K231204 Cochlear™ Osia® System

Aug 18, 2023
113 days to decision

K231204 · Product code: **PFO** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k231204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Apr 27, 2023
Decision date	Aug 18, 2023
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cochlear™ Osia® OSI300 Implant; Cochlear™ Magnet Cassette; Cochlear™ Non-Magnetic Cassette; Cochlear™ Osia® 2(I) Sound Processor; Cochlear™ Osia® Fitting Software 2; Cochlear™ Osia® Smart App

APPLICANT

Company	**Cochlear**
Location	Centennial, CO, US
Contact	Denis DiMartino
Website	http://www.cochlear.com/
510(k) history	3 submissions · 3 cleared · 2023-2025

Cochlear is a global leader in implantable hearing solutions. The company develops and manufactures cochlear implant systems, bone conduction devices, and complementary accessories. Cochlear operates with a manufacturing facility in Centennial, US, and has helped over 700,000 people restore hearing worldwide. Cochlear has received FDA 510(k) clearances from total submissions since 2023. The company specializes in Ear, Nose, Throat devices, including implantable sound processors and surgical instruments. The latest clearance was in 2025, confirming active regulatory engage...