

K191921 Cochlear Osia OSI200 Implant, Cochlear Osia 2 Sound Processor, Osia Fitting Software 2.0, Osia SmartApp, Cochlear Osia Surgical InstrumentsNov 15, 2019
120 days to decisionK191921 · Product code: **PFO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k191921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Jul 18, 2019
Decision date	Nov 15, 2019
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cochlear Americas
Location	Englewood, CO, US
Contact	Chinda Hemmavanh
510(k) history	20 submissions · 20 cleared · 2008-2024

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