

K260902 Cochlear™ Osia® 3(I) Sound Processor

Jul 10, 2026
114 days to decision

K260902 · Product code: **PFO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k260902/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Mar 18, 2026
Decision date	Jul 10, 2026
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary
Other names	Cochlear™ Osia® 3 Sound Processor;Cochlear™ Osia® 3 Charger;Cochlear™ Osia® 3 Aqua+;Cochlear™ Osia® Fitting Software 3;Cochlear™ Osia® Smart App;Cochlear™ Osia® System

APPLICANT

Company	Cochlear Americas
Location	Englewood, CO, US
Contact	Whitney Alexander
510(k) history	21 submissions · 21 cleared · 2008-2026