

K190589 Cochlear Osia OSI100 Implant, Cochlear Osia Sound Processor, Osia Intraoperative Test Software, Osia Fitting Software, Cochlear Osia Surgical InstrumentsJul 3, 2019
118 days to decisionK190589 · Product code: **PFO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k190589/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Active Implantable Bone Conduction Hearing System (PFO) |
| Date received | Mar 7, 2019 |
| Decision date | Jul 3, 2019 |
| Days to decision | 118 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190589/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026