

K220922 Cochlear Osia 2 System, Cochlear Osia OSI200 Implant, Cochlear Osia 2 Sound Processor, Cochlear Osia Fitting Software 2, Cochlear MRI KitJul 27, 2022
118 days to decisionK220922 · Product code: PFO · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k220922/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Active Implantable Bone Conduction Hearing System (PFO) |
| Date received | Mar 31, 2022 |
| Decision date | Jul 27, 2022 |
| Days to decision | 118 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

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