

K223803 Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System

Mar 24, 2023
95 days to decision

K223803 · Product code: **QPP** · Orthopedic
Source: <https://www.510kdatabase.net/k223803/>

SUBMISSION DETAILS

| | |
|-----------------------|-------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Post-surgical Kinematic Measurement Knee Device (QPP) |
| Date received | Dec 19, 2022 |
| Decision date | Mar 24, 2023 |
| Days to decision | 95 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Canary Medical USA, LLC |
| Location | Carlsbad, CA, US |
| Contact | Kevin Leung |
| 510(k) history | 3 submissions · 3 cleared · 2022-2024 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k223803/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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