

K192156 Cartiva SCI instrumentation set

Sep 4, 2019
26 days to decision

K192156 · Product code: **QBO** · Orthopedic
Source: <https://www.510kdatabase.net/k192156/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Instruments Designed For Press-fit Osteochondral Implants (QBO) |
| Date received | Aug 9, 2019 |
| Decision date | Sep 4, 2019 |
| Days to decision | 26 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cartiva, Inc. |
| Location | Alpharetta, GA, US |
| Contact | Shriya Kafle |
| 510(k) history | 3 submissions · 3 cleared · 2014-2019 |
