

K192863 MONDRIAN Lumbar Interbody Fusion Cage SystemAug 26, 2020
324 days to decisionK192863 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k192863/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Oct 7, 2019 |
| Decision date | Aug 26, 2020 |
| Days to decision | 324 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ctl Medical Corporation |
| Location | Addison, TX, US |
| Contact | Sean Suh |
| 510(k) history | 14 submissions · 14 cleared · 2017-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192863/> 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 26, 2026