

K182507 Tigon Medical Tissue AnchorsJan 21, 2019
131 days to decisionK182507 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k182507/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Sep 12, 2018 |
| Decision date | Jan 21, 2019 |
| Days to decision | 131 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tigon Medical |
| Location | Severna Park, MD, US |
| Contact | Jeremy Clark |
| Website | https://tigonmedical.com |
| 510(k) history | 7 submissions · 7 cleared · 2019-2026 |

Tigon Medical designs and sells surgical implants, instruments, and suture for the sports medicine industry. Founded in 2017, the company is focused on delivering innovative suture anchors while minimizing waste in surgical procedures. The company operates with a manufacturing facility in Severna Park, Maryland. Tigon Medical has received FDA 510(k) clearances from total submissions, with all submissions focused on Orthopedic devices. The company's regulatory track record spans from 2019 to 2026, demonstrating sustained activity in the orthopedic surgical implant space. R...
