

K211049 Tigon Medical Button SystemAug 4, 2021
118 days to decisionK211049 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k211049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 8, 2021
Decision date	Aug 4, 2021
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	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...