

K193165 MectaFix CL Fixation Button with Continuous LoopFeb 10, 2020
87 days to decisionK193165 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k193165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 15, 2019
Decision date	Feb 10, 2020
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medacta International S.A.
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026

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