

K243665 Crius PEEK Suture Anchor System (Thread-Fix Anchor)Jan 31, 2025
65 days to decisionK243665 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k243665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 27, 2024
Decision date	Jan 31, 2025
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Crius PEEK Suture Anchor System (Thread-Fix Ultra Anchor); Crius PEEK Suture Anchor System (Helicoil Anchor); Crius PEEK Suture Anchor System (Pile Anchor)

APPLICANT

Company	ZheJiang Decans Medical Devices Co., Ltd.
Location	Jiaxing, CN
Contact	Haifeng Liu
510(k) history	6 submissions · 6 cleared · 2024-2026

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