

K232941 Megaloop Button SystemMay 3, 2024
226 days to decisionK232941 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k232941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 20, 2023
Decision date	May 3, 2024
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Endophix Co., Ltd.
Location	Suzhou, CN
Contact	Juan Wu
510(k) history	4 submissions · 4 cleared · 2023-2024

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