

**K232886 INFILoop® Fixed Loop UHMWPE Suture Titanium Button**Nov 8, 2023  
51 days to decisionK232886 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k232886/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 18, 2023
Decision date	Nov 8, 2023
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healthium Medtech Limited</b>
Location	Bangalore, IN
Contact	Pankaj Dawar
510(k) history	5 submissions · 5 cleared · 2023-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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