

**K190774 RIGIDLOOP Titanium Button , RIGIDLOOP Cortical Fixation System XL Implant**

Jul 25, 2019  
121 days to decision

K190774 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k190774/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Mar 26, 2019
Decision date	Jul 25, 2019
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medos International SARL</b>
Location	Raynham, MA, US
Contact	LeeAnn Walosin
510(k) history	96 submissions · 96 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k190774/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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