

K191053 Xtreme-LoopJul 17, 2019
89 days to decisionK191053 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k191053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 19, 2019
Decision date	Jul 17, 2019
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xiros, Ltd.
Location	Leeds, GB
Contact	Stephen Seed
510(k) history	9 submissions · 9 cleared · 2015-2023

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