FDA 510(k) Premarket Notification

K130716 BIORETEC ACTIVASCREW INTERFERENCE

CLEARED

Aug 28, 2013
166 days to decision

K130716 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k130716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Mar 15, 2013
Decision date	Aug 28, 2013
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bioretec, Ltd.**
Location	Tampere, FI
Contact	MARI RUOTSALAINEN
510(k) history	9 submissions · 8 cleared · 2006-2023