K080879 ACTIVATM PRODUCT GROUP INCLUDING BIOABSORBABLE DEVICES ACTIVAPIN FUSION, ACTIVANAILTM CONICALTM

CLEARED

Jun 24, 2008
85 days to decision

K080879 · Product code: **HTY** · Orthopedic
Source: https://www.510kdatabase.net/k080879/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Mar 31, 2008
Decision date	Jun 24, 2008
Days to decision	85 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