FDA 510(k) Premarket Notification

K050766 EXPLANT OSTEONECROSIS INTERVENTION IMPLANT REMOVAL SYSTEM

CLEARED

May 26, 2005
62 days to decision

K050766 · Product code: **HWE** · Orthopedic
Source: https://www.510kdatabase.net/k050766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Orthopedic, Ac-powered Motor And Accessory/attachment (HWE)
Date received	Mar 25, 2005
Decision date	May 26, 2005
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Trabecular**
Location	Allendale, NJ, US
Contact	MARCI HALEVI
510(k) history	10 submissions · 10 cleared · 2004-2006