FDA 510(k) Premarket Notification

K102324 ENDOFUSE INTRA-OSSEOUS FUSION SYSTEM

CLEARED

May 4, 2011
260 days to decision

K102324 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k102324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 17, 2010
Decision date	May 4, 2011
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wrightmedicaltechnologyinc**
Location	Arlington, TN, US
Contact	SARAH HOLTGREWE
510(k) history	302 submissions · 291 cleared · 1993-2023