FDA 510(k) Premarket Notification

K190543 Cannulated Hemi Implant

CLEARED

May 31, 2019
88 days to decision

K190543 · Product code: **KWD** · Orthopedic
Source: https://www.510kdatabase.net/k190543/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Mar 4, 2019
Decision date	May 31, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vilex IN Tennessee, Inc.**
Location	Lakewood Ranch, FL, US
Contact	Sylvia Southard
510(k) history	7 submissions · 7 cleared · 2014-2019