FDA 510(k) Premarket Notification

K081284 VARIAX DISTAL FIBULA PLATE

CLEARED

Jul 18, 2008
73 days to decision

K081284 · Product code: **KTT** · Orthopedic
Source: https://www.510kdatabase.net/k081284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	May 6, 2008
Decision date	Jul 18, 2008
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Howmedica Osteonics Corp.**
Location	Allendale, NJ, US
Contact	ANDREA M DWYER
510(k) history	288 submissions · 288 cleared · 1999-2020