FDA 510(k) Premarket Notification

K094025 CRESCENT SPINAL SYSTEM

CLEARED

Apr 26, 2010
117 days to decision

K094025 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k094025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 30, 2009
Decision date	Apr 26, 2010
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek**
Location	Memphis, TN, US
Contact	JENNIFER HACKNEY
510(k) history	154 submissions · 147 cleared · 2002-2021