FDA 510(k) Premarket Notification

K200606 O-Genesis Graft Delivery System

CLEARED

May 1, 2020
53 days to decision

K200606 · Product code: **FMF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200606/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 9, 2020
Decision date	May 1, 2020
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthofix, Inc.**
Location	Mckinney, TX, US
Contact	Troy Brooks
510(k) history	57 submissions · 57 cleared · 1996-2024