FDA 510(k) Premarket Notification

K200017 Eclipse DermaFlex Cannula

CLEARED

Nov 5, 2020
307 days to decision

K200017 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k200017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 3, 2020
Decision date	Nov 5, 2020
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eclipse Medcorp, LLC**
Location	The Colony, TX, US
Contact	John Tepper
510(k) history	4 submissions · 4 cleared · 2020-2022