FDA 510(k) Premarket Notification

K240185 Cypris eXact Suture Placement Device

CLEARED

May 3, 2024
101 days to decision

K240185 · Product code: **GEJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Carrier, Ligature (GEJ)
Date received	Jan 23, 2024
Decision date	May 3, 2024
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cypris Medical**
Location	Chicago, IL, US
Contact	Dan Holton
510(k) history	2 submissions · 2 cleared · 2024-2024