FDA 510(k) Premarket Notification

K232934 Sunsphere

CLEARED

May 30, 2024
253 days to decision

K232934 · Product code: **KRD** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k232934/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 20, 2023
Decision date	May 30, 2024
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hangzhou Yangshun Medical Technology Co.,Ltd**
Location	Hangzhou, CN
Contact	Hui Dong
510(k) history	1 submissions · 1 cleared · 2024-2024