FDA 510(k) Premarket Notification

K220010 Daylily Single Use Sterile Embryo Transfer Catheter

CLEARED

Dec 16, 2022
346 days to decision

K220010 · Product code: **MQF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k220010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Jan 4, 2022
Decision date	Dec 16, 2022
Days to decision	346 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Horizon Medical Technology Co., Ltd.**
Location	Shanghai, CN
Contact	Beibei Xing
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Microport Group Co., Ltd.**
Contact	Zhixuan Zhang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov