FDA 510(k) Premarket Notification

K201697 Umbilical Vessels Catheter

CLEARED

May 6, 2021
318 days to decision

K201697 · Product code: **FOS** · General Hospital
Source: https://www.510kdatabase.net/k201697/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Umbilical Artery (FOS)
Date received	Jun 22, 2020
Decision date	May 6, 2021
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Haolang Medical USA Corporation**
Location	Bellevue, WA, US
Contact	Lisa Xu
510(k) history	3 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Field Fu

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