FDA 510(k) Premarket Notification

K200426 Acute Dual Lumen Hemodialysis Catheter

CLEARED

Dec 24, 2020
307 days to decision

K200426 · Product code: **MPB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k200426/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Feb 21, 2020
Decision date	Dec 24, 2020
Days to decision	307 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Health Line International Corporation**
Location	Clearfield, UT, US
Contact	Aaron G. Faulkner
510(k) history	11 submissions · 9 cleared · 2006-2023