FDA 510(k) Premarket Notification

K232314 Hood (DH-106STL, DH-116STL, DH-126STL, DH-096ST)

CLEARED

Sep 1, 2023
30 days to decision

K232314 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232314/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Aug 2, 2023
Decision date	Sep 1, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Healthcare Americas Corporation**
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	12 submissions · 12 cleared · 2023-2025