FDA 510(k) Premarket Notification

K231497 Choledochoscope System

CLEARED

Mar 6, 2024
287 days to decision

K231497 · Product code: **FBN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k231497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	May 24, 2023
Decision date	Mar 6, 2024
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen HugeMed Medical Technical Development Co., Ltd.**
Location	Shenzhen, CN
Contact	Cathy Shi
510(k) history	7 submissions · 7 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Chonconn Medical Device Consulting Co., Ltd.**
Contact	Yang Jie

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