FDA 510(k) Premarket Notification

K232245 VedDilator ^TM (3-Stage Balloon Dilation Catheter)

CLEARED

Feb 15, 2024
202 days to decision

K232245 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232245/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 28, 2023
Decision date	Feb 15, 2024
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangsu Vedkang Medical Science and Technology Co., Ltd.**
Location	Changzhou, CN
Contact	Bao Tian
510(k) history	7 submissions · 7 cleared · 2022-2024