FDA 510(k) Premarket Notification

K241801 Tornus ES

CLEARED

Dec 17, 2024
179 days to decision

K241801 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 21, 2024
Decision date	Dec 17, 2024
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Asahi Intecc Co., Ltd.**
Location	Seto-Shi, JP
Contact	Katsuhiko Fujimura
Website	https://www.asahi-intecc.com
510(k) history	83 submissions · 83 cleared · 2003-2026

REGULATORY CONSULTANT

Consulting firm	**Cardiomed Device Consultants**
Contact	Candace Cederman

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