FDA 510(k) Premarket Notification

K933200 OLYMPUS PBD STENTS

CLEARED

Apr 5, 1995
643 days to decision

K933200 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k933200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 1, 1993
Decision date	Apr 5, 1995
Days to decision	643 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	BARRY E SANDS
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k933200/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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