FDA 510(k) Premarket Notification

K833268 ENDOSCOPIC OVERTUBE

CLEARED

Oct 31, 1983
40 days to decision

K833268 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k833268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Sep 21, 1983
Decision date	Oct 31, 1983
Days to decision	40 days
Third-party review	No

APPLICANT

Company	**Mill-Rose Laboratory**
Location	Mchenry, IL, US
510(k) history	46 submissions · 44 cleared · 1979-1998