FDA 510(k) Premarket Notification

K100081 ENTEROSCOPY OVERTUBE, MODEL 00712140

CLEARED

Apr 12, 2010
90 days to decision

K100081 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k100081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jan 12, 2010
Decision date	Apr 12, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**United States Endoscopy Group, Inc.**
Location	Mentor, OH, US
Contact	BOB BISHUI
510(k) history	94 submissions · 92 cleared · 1991-2020