

K130148 FOREIGN BODY HOODAug 7, 2013
197 days to decisionK130148 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k130148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Jan 22, 2013
Decision date	Aug 7, 2013
Days to decision	197 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026