FDA 510(k) Premarket Notification

# K130148 FOREIGN BODY HOOD

**CLEARED**

Aug 7, 2013
197 days to decision

K130148 · 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 |