FDA 510(k) Premarket Notification

K183428 Avulsion Forceps

CLEARED

Apr 16, 2019
126 days to decision

K183428 · Product code: **KGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183428/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Forceps, Biopsy, Electric (KGE)
Date received	Dec 11, 2018
Decision date	Apr 16, 2019
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**STERIS Corporation**
Location	Mentor, OH, US
Contact	Eileen McCafferty
510(k) history	204 submissions · 202 cleared · 1997-2026