FDA 510(k) Premarket Notification

CLEARED

K123319 GYRUS ACMI BICOAG HEMOSTASIS PROBE

Dec 14, 2012
49 days to decision

K123319 · Product code: **KNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k123319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Oct 26, 2012
Decision date	Dec 14, 2012
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Surgical Technologies America**
Location	Southborough, MA, US
Contact	NEIL KELLY
510(k) history	12 submissions · 12 cleared · 2012-2024