

**K141991 SINGLE USE PRELOADED SPHINCTEROTOME V
(DISTAL WIREGUIDED)**

Mar 31, 2015
252 days to decision

K141991 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k141991/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jul 22, 2014
Decision date	Mar 31, 2015
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary
Other names	SINGLE USE SP

APPLICANT

Company	Olympus Medical Systems Copr.
Location	Center Valley, PA, US
Contact	DAPHNEY GERMAIN-KOLAWOLE
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k141991/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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