FDA 510(k) Premarket Notification

CLEARED

K131614 REPROCESSED CLOSUREFAST RADIOFREQUENCY CATHETER 60CM, REPROCESSED CLOSUREFAST RADIOFREQUENCY CATHETER 100CM

Aug 29, 2013
87 days to decision

K131614 · Product code: **NUJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k131614/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (NUJ)
Date received	Jun 3, 2013
Decision date	Aug 29, 2013
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien**
Location	North Haven, CT, US
Contact	Daniel Campion
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...