FDA 510(k) Premarket Notification

K032820 MODIFICATION TO ENDOSCOPIC PLICATION SYSTEM

CLEARED

Oct 23, 2003
43 days to decision

K032820 · Product code: **ODE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k032820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE)
Date received	Sep 10, 2003
Decision date	Oct 23, 2003
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ndo Surgical, Inc.**
Location	Mansfield, MA, US
Contact	ERIC BANNON
510(k) history	6 submissions · 6 cleared · 2003-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k032820/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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