

K023234 ENDOSCOPIC PLICATION SYSTEMApr 17, 2003
202 days to decisionK023234 · Product code: **ODE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k023234/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE) |
| Date received | Sep 27, 2002 |
| Decision date | Apr 17, 2003 |
| Days to decision | 202 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 |

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