

**K030170 REUSABLE SMARTSTITCH SUTURE DEVICE,
MODELS OM-8007, OM-8500**Jul 28, 2003
192 days to decisionK030170 · Product code: **OCW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k030170/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Jan 17, 2003
Decision date	Jul 28, 2003
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Opus Medical, Inc.
Location	Albuquerque,, NM, US
Contact	JAMES W HART
510(k) history	13 submissions · 13 cleared · 2001-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030170/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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