

K022229 SMARTSTITCH SUTURE DEVICE, MODEL OM-8500Sep 6, 2002
58 days to decisionK022229 · Product code: **OCW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k022229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Jul 10, 2002
Decision date	Sep 6, 2002
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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