

K023843 SMARTSTITCH M-CONNECTOR, MODEL OM-8005Feb 14, 2003
88 days to decisionK023843 · Product code: **OCW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k023843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Nov 18, 2002
Decision date	Feb 14, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement
Other names	SMARTSTITCH ACTUATION HANDLE, MODEL OM-8500; AND SMARTSTITCH SUTURE CARTRIDGE

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/k023843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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