

**K033317 SMARTSTITCH M-CONNECTOR, MODEL OM-8700**Dec 30, 2003  
76 days to decisionK033317 · Product code: **OCW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k033317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Oct 15, 2003
Decision date	Dec 30, 2003
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement
Other names	NEEDLE CASSETTE, OM-8750; AUTOCUFF SYSTEM INSTRUMENT SET, OM-9070

**APPLICANT**

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Company	<b>Opus Medical, Inc.</b>
Location	Albuquerque,, NM, US
Contact	LAURA N KASPEROWICZ
510(k) history	13 submissions · 13 cleared · 2001-2004

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