

K001328 INTRODUCER SHEATHJul 17, 2000
82 days to decisionK001328 · Product code: **FEC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k001328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Obturator, For Endoscope (FEC)
Date received	Apr 26, 2000
Decision date	Jul 17, 2000
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Novasys Medical, Inc.
Location	Sunnyvale, CA, US
Contact	THOMAS C WEHMAN
510(k) history	5 submissions · 5 cleared · 2000-2004

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