

K100746 FIBER ONEJun 11, 2010
87 days to decisionK100746 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 16, 2010
Decision date	Jun 11, 2010
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems
Location	Minnetonka, MN, US
Contact	DARLENE CROCKETT-BILLIG
Website	http://www.varian.com
510(k) history	10 submissions · 10 cleared · 2008-2014

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