

**K964561 ENDOLUMINA II TRANSILLUMINATION SYSTEM 56FR
E-5630, 50FR E-5030 AND 40FR E-4020, ENDOLUMINA II
DETACHABLE TIPS, 56FR, TA**Feb 11, 1997
90 days to decisionK964561 · Product code: **FDG** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor, Fiberoptic (FDG)
Date received	Nov 13, 1996
Decision date	Feb 11, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioenterics Corp.
Location	Carpinteria, CA, US
Contact	KEITH LOWREY
510(k) history	4 submissions · 4 cleared · 1992-2001

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