

K091962 POLYSCOPE FLEXIBLE ENDOSCOPY CATHETERSep 30, 2009
91 days to decisionK091962 · Product code: **ODF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k091962/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mini Endoscope, Gastroenterology-urology (ODF)
Date received	Jul 1, 2009
Decision date	Sep 30, 2009
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary
Other names	10,000 PIXEL FIBER OPTIC; XENON LIGHT SOURCE, MODEL LS-200

APPLICANT

Company	Lumenis, Inc.
Location	Mchenry, IL, US
Contact	MIKE AYMAMI
510(k) history	43 submissions · 43 cleared · 1979-2022

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