

K964522 ELLIPSE 4Mar 21, 1997
129 days to decisionK964522 · Product code: **FEN** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Nov 12, 1996
Decision date	Mar 21, 1997
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Andromeda Medizinische Systeme GmbH
Location	Potomac, MD, US
Contact	NORMAN F ESTRIN, PH.D. , RAC
510(k) history	1 submissions · 1 cleared · 1997-1997

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