

K930135 SILICONE RECTAL BALLOONOct 8, 1993
269 days to decisionK930135 · Product code: **FEN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k930135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Jan 12, 1993
Decision date	Oct 8, 1993
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Urological, Inc.
Location	Spencer, IN, US
Contact	TAMMY BACON
510(k) history	104 submissions · 102 cleared · 1986-2011

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