

**K972964 ATRION MEDICAL BALLOON CATHETER INFLATION
DEVICE**Oct 10, 1997
60 days to decisionK972964 · Product code: **KOE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k972964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Aug 11, 1997
Decision date	Oct 10, 1997
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Atrion Medical Products, Inc.
Location	Arab, AL, US
Contact	DAN CLARK
510(k) history	9 submissions · 9 cleared · 1997-2006

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