

**K913477 APEX(TM) PROSTATIC BALLOON DILATION  
CATHETER**Dec 27, 1991  
144 days to decisionK913477 · Product code: **KOE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k913477/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Aug 5, 1991
Decision date	Dec 27, 1991
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Peripheral Systems Group</b>
Location	Mountain View, CA, US
Contact	JESSICA AYRES
510(k) history	17 submissions · 17 cleared · 1990-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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