FDA 510(k) Premarket Notification

K913477 APEX(TM) PROSTATIC BALLOON DILATION CATHETER

CLEARED

Dec 27, 1991
144 days to decision

K913477 · Product code: **KOE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k913477/

SUBMISSION DETAILS

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

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