FDA 510(k) Premarket Notification

K920551 120 FR OPTILUME PROSTATE BALLOON DILATOR

CLEARED

Oct 28, 1992
265 days to decision

K920551 · Product code: **KOE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k920551/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Feb 6, 1992
Decision date	Oct 28, 1992
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Medical Systems, Inc.**
Location	Mchenry, IL, US
Contact	SUSAN TESMER
510(k) history	72 submissions · 72 cleared · 1979-2013