FDA 510(k) Premarket Notification

K913365 ACCUSCOPE(TM) & ACCUSCOPE II(TM)

CLEARED

Apr 27, 1992
273 days to decision

K913365 · Product code: **HEX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k913365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Jul 29, 1991
Decision date	Apr 27, 1992
Days to decision	273 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Vineland Medical Products, Inc.**
Location	Vineland, NJ, US
Contact	DON PASQUALE
510(k) history	1 submissions · 1 cleared · 1992-1992