FDA 510(k) Premarket Notification

K954791 SEMINAL FLUID COLLECTION KIT II

CLEARED

Jan 5, 1996
79 days to decision

K954791 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k954791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Oct 18, 1995
Decision date	Jan 5, 1996
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Apex Medical Technologies, Inc.**
Location	San Diego, CA, US
Contact	STEFANIE BEDARD
510(k) history	8 submissions · 8 cleared · 1987-2012