FDA 510(k) Premarket Notification

K926425 AMNIPERF(TM)

CLEARED

Mar 7, 1994
439 days to decision

K926425 · Product code: **HGE** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k926425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amniotome (HGE)
Date received	Dec 23, 1992
Decision date	Mar 7, 1994
Days to decision	439 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Raymart Development Co.**
Location	Atlanta, GA, US
Contact	DENNIS L NELSON
510(k) history	1 submissions · 1 cleared · 1994-1994