FDA 510(k) Premarket Notification

K894432 MODIFIED HAM'S F-10 W/ALBUMIN

CLEARED

Sep 22, 1989
67 days to decision

K894432 · Product code: **HDR** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k894432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cap, Cervical (HDR)
Date received	Jul 17, 1989
Decision date	Sep 22, 1989
Days to decision	67 days
Third-party review	No

APPLICANT

Company	**Irvine Scientific**
Location	Mchenry, IL, US
Contact	PAUL WEATHERSBEE,PHD
510(k) history	16 submissions · 16 cleared · 1982-2016