FDA 510(k) Premarket Notification

K875137 LAPAROFLATOR 3000, STANDARD AND ELECTRONIC

CLEARED

Mar 2, 1988
78 days to decision

K875137 · Product code: **HES** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k875137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Carbon-dioxide, Uterotubal (and Accessories) (HES)
Date received	Dec 15, 1987
Decision date	Mar 2, 1988
Days to decision	78 days
Third-party review	No

APPLICANT

Company	**F.M. Wiest USA, Inc.**
Location	Cherry Hill, NJ, US
Contact	WAYNE W DISANZA
510(k) history	12 submissions · 12 cleared · 1986-1994