FDA 510(k) Premarket Notification

K963872 FEMRX MORCELLATOR SYSTEM

CLEARED

Jan 17, 1997
113 days to decision

K963872 · Product code: **HET** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k963872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Sep 26, 1996
Decision date	Jan 17, 1997
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gynecare Innovation Center**
Location	Sunnyvale, CA, US
Contact	MICHAEL A DANIEL
510(k) history	8 submissions · 8 cleared · 1996-1998