FDA 510(k) Premarket Notification

K952483 LEEP SYSTEM 1000

CLEARED

Oct 6, 1995
129 days to decision

K952483 · Product code: **HGI** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k952483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocautery, Gynecologic (and Accessories) (HGI)
Date received	May 30, 1995
Decision date	Oct 6, 1995
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**CooperSurgical, Inc.**
Location	Mountain View, CA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	41 submissions · 40 cleared · 1991-2025