

K952483 LEEP SYSTEM 1000Oct 6, 1995
129 days to decisionK952483 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026