FDA 510(k) Premarket Notification

K050639 LUMENIS VERSACUT TISSUE MORCELLATOR SYSTEM

CLEARED

Mar 31, 2005
17 days to decision

K050639 · Product code: **GCJ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k050639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Mar 14, 2005
Decision date	Mar 31, 2005
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lumenis, Inc.**
Location	Mchenry, IL, US
Contact	MARTHA MURARI
510(k) history	43 submissions · 43 cleared · 1979-2022