FDA 510(k) Premarket Notification

K003824 OMNISONICS ULTRASONIC SURGERY SYSTEM, MODEL STI

CLEARED

Mar 8, 2001
87 days to decision

K003824 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003824/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Dec 11, 2000
Decision date	Mar 8, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omnisonics Medical Technologies**
Location	Wilmington, MA, US
Contact	DOUG CHARLAND
510(k) history	8 submissions · 8 cleared · 1999-2008