FDA 510(k) Premarket Notification

CLEARED

K032690 MISONIX INC. FS 1000 RF ULTRASONIC SURGICAL ASPIRATOR SYSTEM

Dec 9, 2003
98 days to decision

K032690 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k032690/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Sep 2, 2003
Decision date	Dec 9, 2003
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Misonix, Inc.**
Location	Farmingdale, NY, US
Contact	RONALD R MANNA
Website	http://www.misonix.com/
510(k) history	17 submissions · 17 cleared · 1998-2022

Misonix, Inc. specializes in ultrasonic surgical and wound care devices, with a manufacturing facility in Farmingdale, US. The company developed core technologies for minimally invasive surgical applications and therapeutic ultrasound systems. Misonix received FDA 510(k) clearances from total submissions between 1998 and 2022. All cleared devices fall within the General & Plastic Surgery category. The company's regulatory record reflects sustained focus on ultrasonic surgical aspirators, lesion-generating systems, and ultrasonic wound care platforms. The company is inacti...