FDA 510(k) Premarket Notification

CLEARED

K221235 neXus Ultrasonic Surgical Aspirator System

Jul 28, 2022
90 days to decision

K221235 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221235/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Apr 29, 2022
Decision date	Jul 28, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Misonix, Inc.**
Location	Farmingdale, NY, US
Contact	John Salerno
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...

REGULATORY CONSULTANT

Consulting firm	**Misonix**
Contact	John Salerno

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov