

K212060 neXus Ultrasonic Surgical Aspirator SystemDec 13, 2021
165 days to decisionK212060 · Product code: **LFL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Jul 1, 2021
Decision date	Dec 13, 2021
Days to decision	165 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...