FDA 510(k) Premarket Notification

K020853 NUVASIVE MESH

CLEARED

Jun 13, 2002
90 days to decision

K020853 · Product code: **EZX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k020853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Metal (EZX)
Date received	Mar 15, 2002
Decision date	Jun 13, 2002
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nuvasive, Inc.**
Location	San Diego, CA, US
Contact	LAETITIA BERNARD
Website	http://www.nuvasive.com/
510(k) history	91 submissions · 90 cleared · 1999-2024

NuVasive, Inc. is a medical device company headquartered in San Diego, California. The company develops and markets surgical solutions focused on spine and orthopedic procedures. NuVasive operates globally and serves healthcare professionals and patients worldwide. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Orthopedic devices represent the dominant category, accounting for the majority of the company's cleared submissions. The most recent clearance was granted in 2024, demonstrating continued r...