FDA 510(k) Premarket Notification

K233706 Bendini Cloud Application

CLEARED

Aug 2, 2024
256 days to decision

K233706 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k233706/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 20, 2023
Decision date	Aug 2, 2024
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nuvasive**
Location	San Diego, CA, US
Contact	Meet Vaghani
Website	http://www.nuvasive.com/
510(k) history	1 submissions · 1 cleared · 2024-2024

NuVasive is a medical device company headquartered in San Diego, California. The company develops and delivers solutions for spine surgery and orthopedic procedures. NuVasive operates globally with a strong presence across multiple international markets. The company has received FDA 510(k) clearance from total submission. NuVasive specializes in Orthopedic devices, which represent 100% of its regulatory submissions. The company achieved its first FDA 510(k) clearance in 2024 and remains active in the regulatory space. NuVasive's cleared portfolio includes advanced surgica...