FDA 510(k) Premarket Notification

CLEARED

K222988 neoWave LS Lumbar Straight, neoWave C Cervical, and Ti3D Cervical

Sep 1, 2023
338 days to decision

K222988 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k222988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 28, 2022
Decision date	Sep 1, 2023
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ht Medical D.B.A. Xenix Medical**
Location	Orlando, FL, US
Contact	Ryan Phillips
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**MCRA**
Contact	Justin Eggleton

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