FDA 510(k) Premarket Notification

K223190 Hive™ Standalone Cervical System

CLEARED

Dec 12, 2022
60 days to decision

K223190 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k223190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 13, 2022
Decision date	Dec 12, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**NanoHive Medical, LLC**
Location	Woburn, MA, US
Contact	Ian Helmar
Website	https://nanohive.com
510(k) history	3 submissions · 3 cleared · 2022-2026

NanoHive Medical, LLC designs and manufactures bioactive spinal fusion interbody devices with a manufacturing facility in Woburn, Massachusetts. The company specializes in 3D printed titanium implants featuring proprietary Soft Titanium® technology and a patented rhombic dodecahedron lattice structure. NanoHive has received FDA 510(k) clearances from total submissions since 2022. All submissions focus on Orthopedic devices for spinal fusion applications. The company remains active, with its most recent clearance in 2026. The company's product portfolio includes standalone...

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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