

**K231241 NanoHive Medical Lumbar Interbody System**Jul 12, 2023  
75 days to decisionK231241 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k231241/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received         | Apr 28, 2023   |
| Decision date         | Jul 12, 2023   |
| Days to decision      | 75 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>NanoHive Medical, LLC</b>                            |
| Location       | Woburn, MA, US  |
| Contact        | Ian Helmar  |
| Website        | <a href="https://nanohive.com">https://nanohive.com</a> |
| 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**

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|-----------------|-------------------------------|
| Consulting firm | <b>Empirical Technologies</b> |
| Contact         | Nathan Wright                 |

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

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