

K231899 HAtetracell™-C Titanium Cervical IBF SystemOct 17, 2023
111 days to decisionK231899 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k231899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 28, 2023
Decision date	Oct 17, 2023
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovasis, Inc.
Location	Salt Lake City, UT, US
Contact	Michael Thomas
510(k) history	33 submissions · 32 cleared · 2004-2025

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