CLEARED

K220875 HAcancellous PEEK-C Porous HA PEEK Cervical IBF System

Aug 26, 2022
154 days to decision

K220875 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k220875/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Mar 25, 2022
Decision date	Aug 26, 2022
Days to decision	154 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	Marshall McCarty
510(k) history	33 submissions · 32 cleared · 2004-2025