

K231585 Vantage PSI SystemJun 30, 2023
30 days to decisionK231585 · Product code: **OYK** · Orthopedic
Source: <https://www.510kdatabase.net/k231585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ankle Arthroplasty Implantation System (OYK)
Date received	May 31, 2023
Decision date	Jun 30, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Systems, Inc.
Location	Golden, CO, US
Contact	Ashley Dawson
Website	http://www.3dsystems.com/
510(k) history	11 submissions · 11 cleared · 2016-2025

3D Systems, Inc. is a healthcare technology company specializing in personalized medical device solutions. The company operates with a manufacturing facility in Golden, Colorado, and serves orthopedic, neurology, and radiology specialties through advanced 3D printing and imaging technologies. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2016. Orthopedic devices represent the dominant category, including ankle and cranial implant systems. The latest clearance in 2025 confirms continued regulatory activity and product in...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231585/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026