FDA 510(k) Premarket Notification

K241326 Cadence Ankle PSI System

CLEARED

Aug 30, 2024
112 days to decision

K241326 · Product code: **OYK** · Orthopedic
Source: https://www.510kdatabase.net/k241326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ankle Arthroplasty Implantation System (OYK)
Date received	May 10, 2024
Decision date	Aug 30, 2024
Days to decision	112 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...