

K183489 D2PAug 29, 2019
255 days to decisionK183489 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k183489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 17, 2018
Decision date	Aug 29, 2019
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Systems, Inc.
Location	Golden, CO, US
Contact	Kim Torluemke
Website	http://www.3dsystems.com/
510(k) history	12 submissions · 12 cleared · 2016-2026

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...

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Device record: <https://www.510kdatabase.net/k183489/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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