

**K161841 D2P**Jan 9, 2017  
188 days to decisionK161841 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k161841/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 5, 2016
Decision date	Jan 9, 2017
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>3D Systems, Inc.</b>
Location	Golden, CO, US
Contact	KIM TORLUEMKE
Website	<a href="http://www.3dsystems.com/">http://www.3dsystems.com/</a>
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...

---