

K191585 iNtuition-Structural Heart ModuleJul 12, 2019
28 days to decisionK191585 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k191585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 14, 2019
Decision date	Jul 12, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terarecon,Inc.
Location	Pleasant Hill, CA, US
Contact	Megha Jain
510(k) history	14 submissions · 14 cleared · 1998-2025

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