

K152078 Implant Studio 2015Dec 4, 2015
130 days to decisionK152078 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k152078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 27, 2015
Decision date	Dec 4, 2015
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3Shape Medical A/S
Location	Copenhagen, DK
Contact	Hanne Nielsen
510(k) history	3 submissions · 3 cleared · 2014-2020

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