

K202256 3Shape Implant StudioSep 9, 2020
30 days to decisionK202256 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k202256/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 10, 2020
Decision date	Sep 9, 2020
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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