FDA 510(k) Premarket Notification

K202256 3Shape Implant Studio

CLEARED

Sep 9, 2020
30 days to decision

K202256 · 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