FDA 510(k) Premarket Notification

K190074 Presero 3D Scanning System

CLEARED

Feb 14, 2019
29 days to decision

K190074 · Product code: **LLZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k190074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 16, 2019
Decision date	Feb 14, 2019
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Certis Health**
Location	Pompano Beach, FL, US
Contact	Richard Vogel Vogel
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Mark Job

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