FDA 510(k) Premarket Notification

K191688 SubtleMR

CLEARED

Sep 16, 2019
84 days to decision

K191688 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k191688/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 24, 2019
Decision date	Sep 16, 2019
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Subtle Medical, Inc.**
Location	Menlo Park, CA, US
Contact	Ajit Shankaranarayanan
510(k) history	9 submissions · 9 cleared · 2018-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k191688/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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