FDA 510(k) Premarket Notification

K192890 SentEP

CLEARED

Sep 18, 2020
344 days to decision

K192890 · Product code: **LLZ** · Cardiovascular
Source: https://www.510kdatabase.net/k192890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 10, 2019
Decision date	Sep 18, 2020
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sentiar, Inc.**
Location	St. Louis, MO, US
Contact	Berk Tas
510(k) history	2 submissions · 2 cleared · 2020-2023