FDA 510(k) Premarket Notification

K192165 Acteon Imaging Suite

CLEARED

Feb 11, 2020
186 days to decision

K192165 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k192165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 9, 2019
Decision date	Feb 11, 2020
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**De Gotzen S.R.L.**
Location	Olgiate Olona, Varese, IT
Contact	Dario Bandiera
510(k) history	5 submissions · 5 cleared · 2014-2020