

K192165 Acteon Imaging SuiteFeb 11, 2020
186 days to decisionK192165 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026