

K190764 SurgicalARMay 13, 2019
49 days to decisionK190764 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k190764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 25, 2019
Decision date	May 13, 2019
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medivis, Inc.
Location	Brooklyn, NY, US
Contact	Amy Lynn
510(k) history	3 submissions · 3 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190764/> 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 May 25, 2026