

K181939 icobrainNov 6, 2018
110 days to decisionK181939 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k181939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 19, 2018
Decision date	Nov 6, 2018
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Icometrix NV
Location	Leuven, BE
Contact	Jan Verheyden
510(k) history	4 submissions · 4 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181939/> 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 26, 2026