FDA 510(k) Premarket Notification

K181939 icobrain

CLEARED

Nov 6, 2018
110 days to decision

K181939 · 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