

K153736 3mensio WorkstationMay 27, 2016
151 days to decisionK153736 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k153736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 28, 2015
Decision date	May 27, 2016
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pie Medical Imaging BV
Location	Maastricht, NL
Contact	Annemiek Bouts
510(k) history	23 submissions · 23 cleared · 2001-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153736/> 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 14, 2026