

K222320 MedDreamDec 6, 2022
126 days to decisionK222320 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k222320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 2, 2022
Decision date	Dec 6, 2022
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Softneta Uab
Location	Kaunas, LT
Contact	Laura Baroniene
510(k) history	2 submissions · 2 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	Licensale, Inc.
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222320/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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