

K203451 TCL3 Motion Tracking SystemApr 28, 2021
156 days to decisionK203451 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k203451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 23, 2020
Decision date	Apr 28, 2021
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tracinnovations Aps
Location	Ballerup, DK
Contact	Stefan Glimberg
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Sheila Pickering PHD
Contact	Sheila Pickering

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

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