FDA 510(k) Premarket Notification

CLEARED

K202793 Cercare Medical Neurosuite

May 17, 2021
237 days to decision

K202793 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k202793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 22, 2020
Decision date	May 17, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cercare Medical Aps**
Location	Aarhus, DK
Contact	Mikkel Bo Hansen
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**JW Regulatory Consulting, LLC**
Contact	Jennifer Willner

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202793/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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