FDA 510(k) Premarket Notification

K190536 Mediracer NCS

CLEARED

Sep 25, 2019
205 days to decision

K190536 · Product code: **JXE** · Neurology
Source: https://www.510kdatabase.net/k190536/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Nerve Conduction Velocity Measurement (JXE)
Date received	Mar 4, 2019
Decision date	Sep 25, 2019
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mediracer OY**
Location	Oulu, FI
Contact	Lassi Laitinen
510(k) history	1 submissions · 1 cleared · 2019-2019