FDA 510(k) Premarket Notification

K232981 Synq Software Version 1.3

CLEARED

Oct 11, 2023
20 days to decision

K232981 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k232981/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Sep 21, 2023
Decision date	Oct 11, 2023
Days to decision	20 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Synaptive Medical, Inc.**
Location	Toronto On, CA
Contact	Ahmed Hamed
510(k) history	10 submissions · 10 cleared · 2014-2024

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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