FDA 510(k) Premarket Notification

CLEARED

K223875 MOBINEURO Alita Intraoperative MRI System

Mar 20, 2023
87 days to decision

K223875 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k223875/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Dec 23, 2022
Decision date	Mar 20, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Sino Canada Health Engineering Research Institute (Hefei)**
Location	Hefei, CN
Contact	Gong Zhang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Clinical Development Solutionss**
Contact	Danijela Domljanovic

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