

K082964 PRISM ACQUIRE (VERSION 1.5), PRISM PROCESS (VERSION 1.5), PRISM VIEW (VERSION 2.5)

Mar 9, 2009
157 days to decision

K082964 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k082964/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 3, 2008
Decision date	Mar 9, 2009
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Prism Clinical Imaging, Inc.
Location	West Allis, WI, US
Contact	JAMES L REUSS
510(k) history	2 submissions · 2 cleared · 2009-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k082964/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026