K133670 HEADPHONES, PATIENT ALERT, STANDALONE INTERFACE

CLEARED

Jul 24, 2014
237 days to decision

K133670 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k133670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 29, 2013
Decision date	Jul 24, 2014
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neocoil, LLC**
Location	Pewaukee, WI, US
Contact	MICHEAL LEIGH
Website	https://neocoil.com/
510(k) history	17 submissions · 17 cleared · 2007-2026

Neocoil, LLC designs and manufactures high-quality radiofrequency (RF) coils and audio systems for magnetic resonance imaging (MRI) applications. Founded in 2005, the company specializes in improving patient outcomes and imaging quality through innovative coil design and patient comfort solutions. Neocoil operates with a manufacturing facility in Pewaukee, Wisconsin. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. All cleared devices fall within the Radiology category. Neocoil's regulatory history spans from 200...