

**K173409 Wireless Audio System**Feb 16, 2018  
107 days to decisionK173409 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k173409/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 1, 2017
Decision date	Feb 16, 2018
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neocoil, LLC</b>
Location	Pewaukee, WI, US
Contact	Michael Leigh
Website	<a href="https://neocoil.com/">https://neocoil.com/</a>
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...

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