

**K113474 1.5T GEM FLEX COIL**Mar 16, 2012  
115 days to decisionK113474 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k113474/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 22, 2011
Decision date	Mar 16, 2012
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neocoil, LLC</b>
Location	Pewaukee, WI, US
Contact	STEVEN NICHOLS
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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