

**K222407 16ch Breast Coil / 16ch Breast Coils, 1.5T 16ch Breast Coil, 3.0T 16ch Breast Coil, 1.5T 16ch Breast Coil, 3T 16ch Breast Coil**Oct 14, 2022  
66 days to decisionK222407 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k222407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Aug 9, 2022
Decision date	Oct 14, 2022
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neocoil, LLC</b>
Location	Pewaukee, WI, US
Contact	Katie Gonzalez
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...