

K173377 3.0T 16ch Breast CoilNov 28, 2017
29 days to decisionK173377 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k173377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 30, 2017
Decision date	Nov 28, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Neocoil, LLC
Location	Pewaukee, WI, US
Contact	Michael 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...
