FDA 510(k) Premarket Notification

K182958 1.5T 16ch Breast Coil

CLEARED

Nov 16, 2018
23 days to decision

K182958 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k182958/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 24, 2018
Decision date	Nov 16, 2018
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neocoil, LLC**
Location	Pewaukee, WI, US
Contact	Katie Gonzalez
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182958/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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