FDA 510(k) Premarket Notification

CLEARED

Mar 11, 2022
108 days to decision

K213687 32Ch AIR Open Coil Suite: 1.5T AIR Open Head Neck Posterior 9ch / 3.0T AIR Open Head Neck Posterior 9ch, 1.5T AIR Open Neck Chest Anterior 7ch / 3.0T AIR Open Neck Chest Anterior 7ch, 1.5T AIR Open Head Anterior 16ch / 3.0T AIR Open Head Anterior 16ch

K213687 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k213687/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 23, 2021
Decision date	Mar 11, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	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/k213687/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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