

**K160350 ECG CT Gating Device**Jun 16, 2016  
129 days to decisionK160350 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k160350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Feb 8, 2016
Decision date	Jun 16, 2016
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neocoil, LLC</b>
Location	Pewaukee, WI, US
Contact	MICHAEL LEIGH
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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