

**K203677 ViewPoint 6**Jan 15, 2021  
29 days to decisionK203677 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k203677/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 17, 2020
Decision date	Jan 15, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GE Medical Systems Ultrasound &amp; Primary Care Diagnostics, LLC</b>
Location	Wauwatosa, WI, US
Contact	Tracey Ortiz
510(k) history	14 submissions · 14 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203677/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026