

**K183193 MREplus+ Software**Aug 1, 2019  
255 days to decisionK183193 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k183193/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 19, 2018
Decision date	Aug 1, 2019
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Resoundant, Inc.</b>
Location	Rochester, MN, US
Contact	Bernard Horwath
510(k) history	2 submissions · 2 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hrg</b>
Contact	Bernard Horwath

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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