

**K211098 Breast Volume Navigator (BVN) Model G-2000**May 26, 2021  
43 days to decisionK211098 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k211098/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 13, 2021
Decision date	May 26, 2021
Days to decision	43 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Metritrack, Inc.</b>
Location	Hillside, IL, US
Contact	Mirela Wohlford
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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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