

**K223085 Miris Human Milk Analyzer (HMA)**Sep 29, 2023  
364 days to decisionK223085 · Product code: **QEI** · Chemistry  
Source: <https://www.510kdatabase.net/k223085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Breast Milk Macronutrients Test System (QEI)
Date received	Sep 30, 2022
Decision date	Sep 29, 2023
Days to decision	364 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Miris AB</b>
Location	Uppsala, SE
Contact	Elin Hallen
510(k) history	2 submissions · 1 cleared · 2018-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovell US LLP</b>
Contact	John J Smith

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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