

**K240642 SMART Bun-Yo-Matic CT**Jun 20, 2024  
106 days to decisionK240642 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k240642/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 6, 2024
Decision date	Jun 20, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Disior, Ltd.</b>
Location	Helsinki Uusimaa, FL, US
Contact	Aarno Jussila
510(k) history	6 submissions · 6 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Paragon 28, Inc.</b>
Contact	Haylie Fast

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240642/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026