

K240736 SMART Bun-Yo-Matic X-RayJul 2, 2024
106 days to decisionK240736 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k240736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 18, 2024
Decision date	Jul 2, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Paragon 28, Inc.
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)

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