

**K241410 EDEN ControlCath**Feb 13, 2025  
272 days to decisionK241410 · Product code: **BSO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k241410/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Conduction, Anesthetic (BSO)
Date received	May 17, 2024
Decision date	Feb 13, 2025
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jmt Co., Ltd.</b>
Location	Yangju-Si, KR
Contact	Sang-Ok Nam
510(k) history	4 submissions · 4 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtech Group, LLC</b>
Contact	Dave Kim

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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