

**K240164 NovaLine SP-C35 Transducer Protector (956007)**Jun 28, 2024  
158 days to decisionK240164 · Product code: **FIB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k240164/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Protector, Transducer, Dialysis (FIB)
Date received	Jan 22, 2024
Decision date	Jun 28, 2024
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bain Medical Equipment (Guangzhou) Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Zoe Zeng
510(k) history	6 submissions · 6 cleared · 2017-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240164/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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