

**K243639 Portare System (FA-001)**Jun 5, 2025  
192 days to decisionK243639 · Product code: **EOB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k243639/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Nasopharyngoscope (flexible Or Rigid) (EOB) |
| Date received         | Nov 25, 2024                                |
| Decision date         | Jun 5, 2025                                 |
| Days to decision      | 192 days                                    |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                     |

**APPLICANT**

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|----------------|---|
| Company        | <b>Grumpy Innovation, Inc.</b>                                  |
| Location       | Sioux Falls, SD, US   |
| Contact        | Sam Sharma  |
| Website        | <a href="https://grumpyinnov.com/">https://grumpyinnov.com/</a> |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025                           |

Grumpy Innovation, Inc. develops advanced wireless endoscopy systems for diagnostic imaging. The company is based in Sioux Falls, US, and specializes in innovative medical device technology that eliminates traditional cable constraints. The company has received FDA 510(k) clearance from total submission. Grumpy Innovation focuses exclusively on Ear, Nose, Throat devices, with its flagship product cleared in 2025. The company remains active, demonstrating ongoing commitment to regulatory compliance and innovation in diagnostic endoscopy. The PORTARE Wireless HD Nasopharyng...