

**K180575 THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type X, THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type X, THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type X**Jul 12, 2018  
129 days to decisionK180575 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k180575/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Mar 5, 2018  |
| Decision date         | Jul 12, 2018   |
| Days to decision      | 129 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Olympus Medical Systems Corp.</b>  |
| Location       | Hachiochi-Shi, JP   |
| Contact        | Toshiyuki Nakajima  |
| Website        | <a href="https://www.olympus-global.com">https://www.olympus-global.com</a> |
| 510(k) history | 101 submissions · 101 cleared · 2012-2026                                   |

Olympus Medical Systems Corp. is a global medical device manufacturer headquartered in Hachiochi-Shi, Japan. The company specializes in endoscopic imaging systems and therapeutic devices for minimally invasive procedures. Olympus has received FDA 510(k) clearances from total submissions since 2012. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including endoscopes, hemostatic forceps, biopsy instruments, and sphincterotomes. The latest clearance in 2026 reflects continued active development and market engagement. Recent cleared dev...