FDA 510(k) Premarket Notification

CLEARED

K254056 THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type S (TB-0545FCS)

Jul 1, 2026
196 days to decision

K254056 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k254056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 17, 2025
Decision date	Jul 1, 2026
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type S (TB-0535FCS); THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type S (TB-0520FCS)

APPLICANT

Company	**Olympus Medical Systems Corp.**
Location	Hachiochi-Shi, JP
Contact	Norikiyo Shibata
Website	https://www.olympus-global.com
510(k) history	103 submissions · 103 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...

REGULATORY CONSULTANT

Consulting firm	**Olympus Corporation of the Americas**
Contact	Susan Lewandowski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov