FDA 510(k) Premarket Notification

K172691 Ultrasonic Generator

CLEARED

Oct 4, 2017
28 days to decision

K172691 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k172691/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Sep 6, 2017
Decision date	Oct 4, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Medical Systems Corp.**
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	https://www.olympus-global.com
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...