FDA 510(k) Premarket Notification

CLEARED

K260580 Single Use Reloadable Clip Applicator (HX-810LR, HX-810UR)

May 21, 2026
90 days to decision

K260580 · Product code: **PKL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k260580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Feb 20, 2026
Decision date	May 21, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Clip (HX-610-090, HX-610-135); Long Clip (HX-610-090L, HX-610-135L); Short Clip (HX-610-090S, HX-610-135S); Super Short Clip (HX-610-135XS)

APPLICANT

Company	**Olympus Medical Systems Corp.**
Location	Hachiochi-Shi, JP
Contact	Seiko Yunoki
Website	https://www.olympus-global.com
510(k) history	102 submissions · 102 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