FDA 510(k) Premarket Notification

K262045 Luja Soft

CLEARED

Jul 7, 2026
20 days to decision

K262045 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k262045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	Jun 17, 2026
Decision date	Jul 7, 2026
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	Troy Thome
Website	http://www.coloplast.com/
510(k) history	72 submissions · 69 cleared · 1983-2026

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...