FDA 510(k) Premarket Notification

K230893 Swiss LthoClast Trilogy

CLEARED

Oct 23, 2023
206 days to decision

K230893 · Product code: **FEO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230893/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Ultrasonic (FEO)
Date received	Mar 31, 2023
Decision date	Oct 23, 2023
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**E.M.S Electro Medical Systems S.A**
Location	North Attleboro, MA, US
Contact	Timothée Deblock
510(k) history	28 submissions · 28 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	**Heyer Regulatory Solutions, LLC**
Contact	Sheila Hemeon-Heyer

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