

K230893 Swiss LthoClast TrilogyOct 23, 2023
206 days to decisionK230893 · Product code: **FEO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, 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](https://accessdata.fda.gov)

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