

K201001 Modulith SLX-F2Mar 30, 2021
348 days to decisionK201001 · Product code: **LNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Apr 16, 2020
Decision date	Mar 30, 2021
Days to decision	348 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Karl Storz Endoscopy America
Location	Los Angeles, CA, US
Contact	Winkie Wong
510(k) history	5 submissions · 5 cleared · 2020-2022

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