

**K243121 SLT Select Fiber Delivery System and Contact Tips
(models: SSRH 8-SMA)**Dec 22, 2024
83 days to decisionK243121 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2024
Decision date	Dec 22, 2024
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TCRH 7-SMA; FEF 2.2-SMA; CFE 0.6-SMA; SSRH 8Z-SMA; SSRH 4-SMA; SSRH 6-SMA; SSRH 9-SMA; SSRH 10-SMA; SSRH 11-SMA; SSRH 7L-SMA; TCRH 7Z-SMA; FEF 1.8-SMA; CFE 0.55-SMA; CFE 0.36-SMA; LAL 550-SMA; LAL 550Z-SMA; LAL 365-SMA; LAL 365Z-SMA; ER2; ERP2; GR2; GRP2; ER4; ERP4; GR4; GRP4; ER6; ERP6; GR6; GRP6; ER8; ERP8; GR8; GRP8; ER10; ERP10; GR10; GRP10; ER12; ERP12; GR12; GRP12; MD2.5; MD3.5; HP1.0; MTP1.5; MTP3.5; MTRG1.5;

APPLICANT

Company	Jiangxi Medex Technology Co., Ltd.
Location	Jiangxi, CN
Contact	Zhang Kaixia
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Microkn Medical Technology Service (Shanghai) Co., Ltd.
Contact	Owen He

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