

K211517 Optica XT Thulium Fiber Laser and Accessories, also known as Optica XT, Optica XT Thulium Fiber Laser, Thulium Fiber Laser 1940 nm, Optica XT Thulium Fiber Laser 1940 nm, Optica XT 60 Thulium Fiber Laser 1940 nm, Optica XT Superpulse Thulium Fiber Laser 1940 nm, OptiLITE Laser Fibers and AccessoriesNov 9, 2021
176 days to decisionK211517 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 17, 2021
Decision date	Nov 9, 2021
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Convergent Laser Technologies
Location	Alameda, CA, US
Contact	Jennifer Mok
510(k) history	2 submissions · 2 cleared · 1999-2021

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