

K161162 Frax 1550 for Ellipse Nordlys/ Ellipse Nordlys+, Ellipse Sirius, Ellipse Infinity, Ellipse Mjolner, Ellipse Nordlys Ultra

Sep 16, 2016
144 days to decision

K161162 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161162/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 25, 2016
Decision date	Sep 16, 2016
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ellipse A/S
Location	Hoersholm, DK
Contact	OLE KOFOD
510(k) history	7 submissions · 7 cleared · 2007-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161162/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026