

**K192951 Ellipse Frax 1940 for Ellipse Nordlys and Ellipse Ydun**Mar 26, 2020  
157 days to decisionK192951 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192951/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 21, 2019
Decision date	Mar 26, 2020
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ellipse A/S</b>
Location	Hoersholm, DK
Contact	Ole Kofod
510(k) history	7 submissions · 7 cleared · 2007-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192951/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 24, 2026