

**K140670 ELLIPSE I2PL+/ELLIPSE MULTIFLEX+**Sep 25, 2014  
191 days to decisionK140670 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k140670/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Mar 18, 2014
Decision date	Sep 25, 2014
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140670/> 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