

K060516 ELLIPSE 12PL, MODEL 9ESL7228May 15, 2006
77 days to decisionK060516 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k060516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 27, 2006
Decision date	May 15, 2006
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Danish Dermatologic Development A/S
Location	Horsholm, DK
Contact	OLE KOFOD
510(k) history	3 submissions · 3 cleared · 2005-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k060516/> 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 30, 2026