

K862865 MODEL 10-C W/LP-10A/U & OB-10A/U FOR ORAL/ENT USEJan 9, 1987
164 days to decisionK862865 · Product code: **EWG** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k862865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Ent Microsurgical Carbon-dioxide (EWG)
Date received	Jul 29, 1986
Decision date	Jan 9, 1987
Days to decision	164 days
Third-party review	No

APPLICANT

Company	Directed Energy, Inc.
Location	Walker, MI, US
Contact	EDWARD JOHANSEN
510(k) history	39 submissions · 38 cleared · 1984-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862865/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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