

K862150 MODEL 8-B WITH OS-1 ATTACHMENT (C02 LASER FOR ENT)Sep 4, 1986
92 days to decisionK862150 · Product code: **EWG** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k862150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Laser, Ent Microsurgical Carbon-dioxide (EWG)
Date received	Jun 4, 1986
Decision date	Sep 4, 1986
Days to decision	92 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

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