

K160195 Forma System, Forma Light SystemApr 15, 2016
79 days to decisionK160195 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jan 27, 2016
Decision date	Apr 15, 2016
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Formatk Systems , Ltd.
Location	Tirat Carmel, IL
Contact	AMIT GOREN
510(k) history	4 submissions · 4 cleared · 2016-2018

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