

**K222352 Epildream HP 4000 MED**Apr 27, 2023  
266 days to decisionK222352 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222352/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 4, 2022
Decision date	Apr 27, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>D.E.A Project S.R.1.</b>
Location	Mapello, IT
Contact	Nico Guerini
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Endo Engineering</b>
Contact	Chiara Violini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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