

**K241358 BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E**

Jun 13, 2024  
30 days to decision

K241358 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k241358/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 14, 2024
Decision date	Jun 13, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sun Pharmaceutical Industries, Inc.</b>
Location	Billerica, MA, US
Contact	Scott Lundahl
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k241358/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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