

**K163638 Dental 5 Multi Diode laser**May 15, 2017  
143 days to decisionK163638 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k163638/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 23, 2016
Decision date	May 15, 2017
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bio-Med USA, Inc.</b>
Location	Paterson, NJ, US
Contact	YOUNG CHI
510(k) history	10 submissions · 10 cleared · 2008-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163638/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026