

**K053087 VISUALASE COOLED LASER APPLICATOR SYSTEM,
LASER DIFFUSING FIBER, COOLING CATHETER SYSTEM**Mar 1, 2006
119 days to decisionK053087 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k053087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 2, 2005
Decision date	Mar 1, 2006
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biotex, Inc.
Location	Houston, TX, US
Contact	ASHOK GOWDA
510(k) history	10 submissions · 10 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053087/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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