

K110434 TRIHEL CO2 LASERApr 19, 2011
63 days to decisionK110434 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k110434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 15, 2011
Decision date	Apr 19, 2011
Days to decision	63 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Beijing Syntech Laser Co., Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	3 submissions · 3 cleared · 2011-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110434/> Data sourced from FDA 510(k) public records (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. - Generated June 9, 2026