FDA 510(k) Premarket Notification

K013021 LIGHTLANCE LASER SKIN PERFORATOR

CLEARED

May 30, 2002
265 days to decision

K013021 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 7, 2001
Decision date	May 30, 2002
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innotech USA, Inc.**
Location	Princeton, NJ, US
Contact	HOWARD HOLSTEIN
510(k) history	3 submissions · 3 cleared · 2000-2004