FDA 510(k) Premarket Notification

K083272 SKINCLEAR Q-SWITCHED ND:YAG LASER

CLEARED

Dec 16, 2008
40 days to decision

K083272 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k083272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 6, 2008
Decision date	Dec 16, 2008
Days to decision	40 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Global USA Distribution, LLC**
Location	Bloomington, MN, US
Contact	MATT MAKOUSKY
510(k) history	4 submissions · 4 cleared · 2008-2008