FDA 510(k) Premarket Notification

K234104 PICOANDY (Q-Switched Nd:YAG Laser)

CLEARED

Mar 15, 2024
80 days to decision

K234104 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k234104/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 26, 2023
Decision date	Mar 15, 2024
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wontech Co., Ltd.**
Location	Daejeon, KR
Contact	Hyunsik Yoon
510(k) history	28 submissions · 28 cleared · 2017-2025