FDA 510(k) Premarket Notification

K202988 Tixel System

CLEARED

Feb 25, 2021
148 days to decision

K202988 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 30, 2020
Decision date	Feb 25, 2021
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Novoxel , Ltd.**
Location	Netanya, IL
Contact	Ronen Shavit
510(k) history	3 submissions · 3 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov