FDA 510(k) Premarket Notification

K222356 Claritag Advanced

CLEARED

May 18, 2023
287 days to decision

K222356 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222356/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Aug 4, 2022
Decision date	May 18, 2023
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dgi Technologies**
Location	Lakewood, NJ, US
Contact	Jeremy Josephson
510(k) history	2 submissions · 2 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Contract In-House Consultants, LLC**
Contact	Marc C Sanchez

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