

K222356 Claritag AdvancedMay 18, 2023
287 days to decisionK222356 · Product code: **GEH** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)

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