

K203032 IcePearl 2.1 CX 90° Needle, IcePearl 2.1 CX L 90° Needle, IcePearl 2.1 CX Needle, IceFORCE 2.1 CX 90° Needle, IceFORCE 2.1 CX L 90° Needle, IceFORCE 2.1 CX NeedleNov 2, 2020
28 days to decisionK203032 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k203032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Oct 5, 2020
Decision date	Nov 2, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Galil Medical, Inc.
Location	Lake Jackson, TX, US
Contact	Amy McKinney
510(k) history	8 submissions · 8 cleared · 2011-2020

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