

K220124 YandR System, VoluDerm Handpiece, VoluDerm TipsFeb 17, 2022
30 days to decisionK220124 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 18, 2022
Decision date	Feb 17, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pollogen, Ltd.
Location	Binyamina, IL
Contact	Sharon Ravid
510(k) history	18 submissions · 18 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	Kathy Maynor
Contact	Kathy Maynor

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

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