

K210529 Dr. Yglo Wart RemoverMay 6, 2021
72 days to decisionK210529 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 23, 2021
Decision date	May 6, 2021
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Theotclab Healthcare B.V.
Location	Amsterdam, NL
Contact	Albert Swane
510(k) history	2 submissions · 2 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Medical Device Approvals, Inc.
Contact	Kathleen Johnson

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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