

K220020 Cryo 7Feb 4, 2022
30 days to decisionK220020 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 5, 2022
Decision date	Feb 4, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer Medizinsysteme GmbH
Location	Neu-Ulm, DE
Contact	Ute Killet
510(k) history	13 submissions · 13 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	Quality and Regulatory Services
Contact	Scott Blood

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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