

K233416 Cryojet Plus (SHE-ACP001-1)Feb 6, 2024
119 days to decisionK233416 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k233416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 10, 2023
Decision date	Feb 6, 2024
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Sano Laser S&T Development Co.,Ltd
Location	Beijing, CN
Contact	Zhang Hongbo
510(k) history	5 submissions · 5 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Microkn Business Consulting (Shanghai) Co., Ltd.
Contact	Zhao Huifang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026