

K230268 ZenPro 40Aug 10, 2023
191 days to decisionK230268 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 31, 2023
Decision date	Aug 10, 2023
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	BLUECORE COMPANY Co., Ltd.
Location	Busan, KR
Contact	Bill Choi
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Bio-Med USA, Inc.
Contact	Young Chi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230268/> 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 26, 2026