FDA 510(k) Premarket Notification

# K212790 XLase Plus

**CLEARED**

Aug 15, 2022
348 days to decision

K212790 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212790/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Sep 1, 2021 |
| Decision date | Aug 15, 2022 |
| Days to decision | 348 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Biotec Italia, Srl** |
| Location | Dueville (Vi), IT |
| Contact | Edoardo Milanello |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Evoskin, LLC** |
| Contact | Mike Berisha |

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