

K210634 MCL 31 Dermablade SystemApr 13, 2022
406 days to decisionK210634 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k210634/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Mar 3, 2021 |
| Decision date | Apr 13, 2022 |
| Days to decision | 406 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Asclepion Laser Technologies GmbH |
| Location | Chelmsford, MA, US |
| Contact | Dania Di Pietro Paolo |
| 510(k) history | 29 submissions · 29 cleared · 2004-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210634/> 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