FDA 510(k) Premarket Notification

# K233709 Exceed Unlimited

**CLEARED**

Feb 23, 2024
95 days to decision

K233709 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233709/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Microneedle Device (QAI) |
| Date received | Nov 20, 2023 |
| Decision date | Feb 23, 2024 |
| Days to decision | 95 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Mt. Derm GmbH** |
| Location | Berlin, DE |
| Contact | Andreas Pachten |
| 510(k) history | 3 submissions · 3 cleared · 2018-2024 |