FDA 510(k) Premarket Notification

# K222210 AEON Endoscopic Stapler

**CLEARED**

Apr 21, 2023
270 days to decision

K222210 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222210/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Staple, Implantable (GDW) |
| Date received | Jul 25, 2022 |
| Decision date | Apr 21, 2023 |
| Days to decision | 270 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Lexington Medical, Inc.** |
| Location | Billerica, MA, US |
| Contact | Rainer Maas |
| 510(k) history | 9 submissions · 9 cleared · 2017-2025 |