

K191436 SaalioOct 18, 2019
141 days to decisionK191436 · Product code: **EGJ** · Physical Medicine
Source: <https://www.510kdatabase.net/k191436/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Iontophoresis, Other Uses (EGJ) |
| Date received | May 30, 2019 |
| Decision date | Oct 18, 2019 |
| Days to decision | 141 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Saalmann Medical GmbH & Co. KG |
| Location | Bad Oeynhausen, DE |
| Contact | Rolf Eilers |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------------|
| Consulting firm | Beo Medconsulting Berlin GmbH |
| Contact | Michael Vent |

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

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