

K243177 SACS PRODec 23, 2024
84 days to decisionK243177 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k243177/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Powered Inflatable Tube (IRP) |
| Date received | Sep 30, 2024 |
| Decision date | Dec 23, 2024 |
| Days to decision | 84 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Elastimed , Ltd. |
| Location | Yokneam Ilit, IL |
| Contact | Zelka Omer |
| 510(k) history | 2 submissions · 2 cleared · 2023-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------------|
| Consulting firm | Hogan Lovells US LLP |
| Contact | John J. Smith |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243177/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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