

K182682 OrthoGold 100Dec 21, 2018
86 days to decisionK182682 · Product code: **ISA** · Physical Medicine
Source: <https://www.510kdatabase.net/k182682/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Therapeutic, Electric (ISA) |
| Date received | Sep 26, 2018 |
| Decision date | Dec 21, 2018 |
| Days to decision | 86 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Tissue Regeneration Technologies |
| Location | Woodstock, GA, US |
| Contact | John Warlick |
| 510(k) history | 2 submissions · 2 cleared · 2018-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | Msquared Associates, Inc. |
| Contact | Jennifer A. Daudelin |

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/k182682/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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