

K112520 US-101L, US-103SOct 26, 2011
56 days to decisionK112520 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k112520/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI) |
| Date received | Aug 31, 2011 |
| Decision date | Oct 26, 2011 |
| Days to decision | 56 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ito Co., Ltd. |
| Location | Brookeville, MD, US |
| Contact | HARUHISA OKADA |
| 510(k) history | 8 submissions · 8 cleared · 1999-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112520/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026