# K070541 IVIVI SOFPULSE, MODELS 912-M10, ROMA3 AND TORINO II

**CLEARED**

Dec 11, 2008
654 days to decision

K070541 · Product code: **ILX** · Physical Medicine
Source: https://www.510kdatabase.net/k070541/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat (ILX) |
| Date received | Feb 26, 2007 |
| Decision date | Dec 11, 2008 |
| Days to decision | 654 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ivivi Technologies, Inc.** |
| Location | Northvale, NJ, US |
| Contact | ANDRE DIMINO |
| 510(k) history | 1 submissions · 1 cleared · 2008-2008 |