

**K150504 GUS ASTRA TEE Transesophageal Probe
Reprocessor, GUS ASTRA VR Endovaginal/Endorectal Probe
Reprocessor**

Nov 16, 2015
263 days to decision

K150504 · Product code: **PSW** · General Hospital
Source: <https://www.510kdatabase.net/k150504/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Liquid (PSW) |
| Date received | Feb 26, 2015 |
| Decision date | Nov 16, 2015 |
| Days to decision | 263 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pci Medical, Inc. |
| Location | Deep River, CT, US |
| Contact | Kevin Mader |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150504/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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