

K181211 Human Tecar HCR 1002Sep 10, 2018
126 days to decisionK181211 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181211/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Vacuum, Radio Frequency Induced Heat (PBX) |
| Date received | May 7, 2018 |
| Decision date | Sep 10, 2018 |
| Days to decision | 126 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Unibell S.R.L |
| Location | Calco, IT |
| Contact | Mario Scerri |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------|
| Consulting firm | THEMA S.r.l. |
| Contact | Marisa Testa |

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/k181211/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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