

K181893 T-PLUSJan 29, 2019
200 days to decisionK181893 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181893/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Vacuum, Radio Frequency Induced Heat (PBX) |
| Date received | Jul 13, 2018 |
| Decision date | Jan 29, 2019 |
| Days to decision | 200 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Wintecare SA |
| Location | Chiasso, CH |
| Contact | Claudio Freti |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181893/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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