

K182094 Family of Venus RF Systems - HealFeb 1, 2019
182 days to decisionK182094 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182094/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Massager, Vacuum, Radio Frequency Induced Heat (PBX) |
| Date received | Aug 3, 2018 |
| Decision date | Feb 1, 2019 |
| Days to decision | 182 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Venus Concept USA, Inc. |
| Location | Sunrise, FL, US |
| Contact | Yoni Iger |
| 510(k) history | 11 submissions · 11 cleared · 2014-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182094/> 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 26, 2026