

**K241107 Indiba Diathermia Radiofrequency Deep Care Device  
(Deep care IDC0409/EVONY )**Jan 24, 2025  
277 days to decisionK241107 · Product code: **PBX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k241107/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Apr 22, 2024
Decision date	Jan 24, 2025
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Indiba Diathermia Radiofrequency Activ Device (Activ ACT0309/CT9)

**APPLICANT**

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Company	<b>Indiba S. A. U.</b>
Location	Sant Quirze Del Vall?s (Barcelona), ES
Contact	Amit Goren
510(k) history	3 submissions · 3 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>A. Stein Regulatory Affairs Consulting Company , Ltd.</b>
Contact	Amit Goren

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241107/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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