

**K242619 GroWell BT Hair Growth System (GW10042)**Dec 2, 2024  
90 days to decisionK242619 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242619/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Sep 3, 2024
Decision date	Dec 2, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Apira Science, Inc.</b>
Location	Chatham, NJ, US
Contact	Ray Pizinger
510(k) history	4 submissions · 4 cleared · 2012-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Feiyang Drug &amp; Medical Consulting Technical Service Group</b>
Contact	Tracy Che

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242619/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026