

**K253396 AYON Body Contouring System™ (AYON SYSTEM)**May 8, 2026  
220 days to decisionK253396 · Product code: **QPB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253396/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | System, Suction, Lipoplasty For Removal (QPB) |
| Date received         | Sep 30, 2025                                  |
| Decision date         | May 8, 2026                                   |
| Days to decision      | 220 days                                      |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Apyx Medical Corporation</b>       |
| Location       | Clearwater, FL, US                    |
| Contact        | Nikita Gajbhiye                       |
| 510(k) history | 6 submissions · 6 cleared · 2022-2026 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253396/> 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 June 6, 2026