

**K151998 TracelT Tissue Marker - 3mL**Aug 19, 2015  
30 days to decisionK151998 · Product code: **NEU** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k151998/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received         | Jul 20, 2015                            |
| Decision date         | Aug 19, 2015                            |
| Days to decision      | 30 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Statement                               |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Augmenix, Inc.</b>                 |
| Location       | Waltham, MA, US                       |
| Contact        | NOEL ROLON                            |
| 510(k) history | 5 submissions · 4 cleared · 2013-2019 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151998/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026