

**K092292 CHECKPOINT**Oct 28, 2009  
91 days to decisionK092292 · Product code: **ETN** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k092292/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Stimulator, Nerve (ETN)            |
| Date received         | Jul 29, 2009                       |
| Decision date         | Oct 28, 2009                       |
| Days to decision      | 91 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Ndi Medical, LLC</b>               |
| Location       | Cleveland, OH, US                     |
| Contact        | JULIE GRILL                           |
| 510(k) history | 3 submissions · 3 cleared · 2006-2015 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092292/> 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 5, 2026