

**K172971 BMLS16-1**Jul 8, 2018  
285 days to decisionK172971 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k172971/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 26, 2017
Decision date	Jul 8, 2018
Days to decision	285 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Biomedical Life Systems, Inc.</b>
Location	Walker, MI, US
Contact	Gary Bussett
510(k) history	35 submissions · 35 cleared · 1984-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172971/> 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 May 30, 2026