

**K030332 MODIFICATION TO BIONICARE STIMULATOR SYSTEM, MODEL BIO-1000**Jun 6, 2003  
126 days to decisionK030332 · Product code: **NYN** · Neurology  
Source: <https://www.510kdatabase.net/k030332/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Special   |
| Device classification | Stimulator, Electrical, Transcutaneous, For Arthritis (NYN) |
| Date received         | Jan 31, 2003  |
| Decision date         | Jun 6, 2003   |
| Days to decision      | 126 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Bionicare Medical Technologies, Inc.</b> |
| Location       | Sparks, MD, US                              |
| Contact        | KENT HOFFMAN                                |
| 510(k) history | 2 submissions · 2 cleared · 2003-2005       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030332/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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