

**K081656 VISUALASE THERMAL THERAPY SYSTEM**Sep 10, 2008  
90 days to decisionK081656 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k081656/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Jun 12, 2008                                 |
| Decision date         | Sep 10, 2008                                 |
| Days to decision      | 90 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biotex, Inc.</b>                     |
| Location       | Houston, TX, US                         |
| Contact        | ROGER MCNICHOLS                         |
| 510(k) history | 10 submissions · 10 cleared · 2006-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081656/> 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 27, 2026