

**K152334 Sungshim Insulin Pen Needle**Mar 17, 2016  
211 days to decisionK152334 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k152334/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received         | Aug 19, 2015                           |
| Decision date         | Mar 17, 2016                           |
| Days to decision      | 211 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Sung Shim Medicare Co., Ltd.</b>   |
| Location       | Sejing-Si, KR                         |
| Contact        | KIM YOUNG KWAN                        |
| 510(k) history | 2 submissions · 2 cleared · 2016-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152334/> 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 2, 2026