

**K070117 SSAFE PLUS DISPOSABLE SAFETY SYRINGE, 3 CC AND 5 CC**

Aug 6, 2007  
206 days to decision

K070117 · Product code: **MEG** · General Hospital  
Source: <https://www.510kdatabase.net/k070117/>

**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Syringe, Antistick (MEG)           |
| Date received         | Jan 12, 2007                       |
| Decision date         | Aug 6, 2007                        |
| Days to decision      | 206 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Dolomite Biotech Sdn Bhd</b>       |
| Location       | San Leandro, CA, US                   |
| Contact        | TIMOTHY LIEW                          |
| 510(k) history | 1 submissions · 1 cleared · 2007-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k070117/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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