

**K081057 INTACT BREAST LESION EXCISION SYSTEM WITH INTACT EXCISION XL**

Jun 17, 2008  
64 days to decision

K081057 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k081057/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Instrument, Biopsy (KNW)           |
| Date received         | Apr 14, 2008                       |
| Decision date         | Jun 17, 2008                       |
| Days to decision      | 64 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Intact Medical Corporation</b>     |
| Location       | Natick, MA, US                        |
| Contact        | DOUGLAS MACARTHUR                     |
| 510(k) history | 4 submissions · 4 cleared · 2006-2016 |

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

Device record: <https://www.510kdatabase.net/k081057/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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