

**K031818 FACILAI VARIOUS MODELS OF SINGLE USE  
ACUPUNCTURE NEEDLE**Dec 3, 2003  
174 days to decisionK031818 · Product code: **MQX** · General Hospital  
Source: <https://www.510kdatabase.net/k031818/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Needle, Acupuncture, Single Use (MQX) |
| Date received         | Jun 12, 2003                          |
| Decision date         | Dec 3, 2003                           |
| Days to decision      | 174 days                              |
| Third-party review    | No                                    |
| Summary / Statement   | Statement                             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Facilai Enterprises , Ltd.</b>     |
| Location       | Hsin Chu City, TW                     |
| Contact        | Ke-Min Jen                            |
| 510(k) history | 1 submissions · 1 cleared · 2003-2003 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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