

**K972883 ISOSAFE EARLOOP PROCEDURE MASK (BLUE, YELLOW)**Feb 26, 1998  
205 days to decisionK972883 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k972883/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | Aug 5, 1997                        |
| Decision date         | Feb 26, 1998                       |
| Days to decision      | 205 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cypress Medical Products, Ltd.</b>   |
| Location       | Mc Henry, IL, US                        |
| Contact        | ANTHONY L GIACCIO                       |
| 510(k) history | 26 submissions · 19 cleared · 1989-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972883/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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