

**K905495 HYSTEROMAT HYSTEROFLATOR HYSTEROSCOPIC INSUFFLATOR**Apr 29, 1991  
143 days to decisionK905495 · Product code: **HIG** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k905495/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Insufflator, Hysteroscopic (HIG)   |
| Date received         | Dec 7, 1990                        |
| Decision date         | Apr 29, 1991                       |
| Days to decision      | 143 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Frigitronics, Inc.</b>             |
| Location       | Mountain View, CA, US                 |
| Contact        | CHARLES L ROSE                        |
| 510(k) history | 3 submissions · 3 cleared · 1991-1991 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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