

**K881505 MAMEX DC MG11**Jun 10, 1988  
60 days to decisionK881505 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k881505/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Mammographic (IZH)  |
| Date received         | Apr 11, 1988                       |
| Decision date         | Jun 10, 1988                       |
| Days to decision      | 60 days                            |
| Third-party review    | No                                 |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Orion Corp.</b>                      |
| Location       | 20101 Turku, FL                         |
| Contact        | JOHN R HOGAN                            |
| 510(k) history | 21 submissions · 20 cleared · 1985-1992 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881505/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 21, 2026