

**K853794 NEOGUARD REFLECTOR**Oct 16, 1985  
35 days to decisionK853794 · Product code: **FMT** · General Hospital  
Source: <https://www.510kdatabase.net/k853794/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Warmer, Infant Radiant (FMT)       |
| Date received         | Sep 11, 1985                       |
| Decision date         | Oct 16, 1985                       |
| Days to decision      | 35 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cas Medical Systems, Inc.</b>                            |
| Location       | Branford, CT, US  |
| Contact        | JOEL N HELFER   |
| Website        | <a href="http://www.casmed.com/">http://www.casmed.com/</a> |
| 510(k) history | 32 submissions · 32 cleared · 1985-2019                     |

Cas Medical Systems, Inc. specialized in cardiovascular devices and critical care monitoring technologies, with a manufacturing facility in Branford, Connecticut. The company developed noninvasive tissue oximetry systems and hemodynamic monitoring solutions for surgical and intensive care settings. The company received FDA 510(k) clearances from total submissions between 1985 and 2019. Its regulatory portfolio focused primarily on tissue oximetry devices for cardiovascular and general surgical applications. The company maintains a strong historical record in critical care...

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