

K862921 MODEL 10200 PREMATURE INFANT INCUBATORApr 1, 1987
243 days to decisionK862921 · Product code: **FMT** · General HospitalSource: <https://www.510kdatabase.net/k862921/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Warmer, Infant Radiant (FMT) |
| Date received | Aug 1, 1986 |
| Decision date | Apr 1, 1987 |
| Days to decision | 243 days |
| Third-party review | No |

APPLICANT

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|----------------|--|
| Company | Rotem Industries C/O Medsys, Inc. |
| Location | Rutherford, NJ, US |
| Contact | MYERS, PHD |
| 510(k) history | 1 submissions · 1 cleared · 1987-1987 |

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