

K070961 BIOMERIX SURGICAL MESH, MODEL: RCR-01Feb 25, 2008
326 days to decisionK070961 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k070961/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mesh, Surgical, Polymeric (FTL) |
| Date received | Apr 5, 2007 |
| Decision date | Feb 25, 2008 |
| Days to decision | 326 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biomerix Corporation |
| Location | Rockville, MD, US |
| Contact | CHRISTINA L KICHULA |
| 510(k) history | 6 submissions · 6 cleared · 2005-2011 |

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