

K970988 FAR-EAST BOUFFANT CAPSJul 10, 1997
114 days to decisionK970988 · Product code: **LYU** · General Hospital
Source: <https://www.510kdatabase.net/k970988/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accessory, Surgical Apparel (LYU) |
| Date received | Mar 18, 1997 |
| Decision date | Jul 10, 1997 |
| Days to decision | 114 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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| Company | Far East Science & Technology Development Co., Ltd. |
| Location | Wuhan, CN |
| Contact | PING JIANG |
| 510(k) history | 3 submissions · 3 cleared · 1997-1997 |

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