

K942200 ISOLYSER OREX SURGEON'S CAPS, HOODS, BOUFFANT CAPS

Aug 7, 1995
459 days to decision

K942200 · Product code: LYU · General Hospital
Source: <https://www.510kdatabase.net/k942200/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Surgical Apparel (LYU)
Date received	May 5, 1994
Decision date	Aug 7, 1995
Days to decision	459 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Thantex Specialties, Inc.
Location	Norcross, GA, US
Contact	THOMAS BONNER
510(k) history	21 submissions · 21 cleared · 1994-1997

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Device record: <https://www.510kdatabase.net/k942200/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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