

**K050193 GERSON 2130/31 TYPE N95 NIOSH CERTIFIED
SURGICAL RESPIRATOR**Apr 11, 2005
74 days to decisionK050193 · Product code: **MSH** · General Hospital
Source: <https://www.510kdatabase.net/k050193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respirator, Surgical (MSH)
Date received	Jan 27, 2005
Decision date	Apr 11, 2005
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Louis M. Gerson Co., Inc.
Location	MA, US
Contact	ROBERT BRUNELL
510(k) history	8 submissions · 8 cleared · 1980-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050193/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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