

**K160271 N95 Particulate Respirator and Surgical Mask, Models
TN01-11 and TN01-12**Jul 15, 2016
164 days to decisionK160271 · Product code: **MSH** · General Hospital
Source: <https://www.510kdatabase.net/k160271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Respirator, Surgical (MSH)
Date received	Feb 2, 2016
Decision date	Jul 15, 2016
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	San-M Package Co., Ltd.
Location	Shimada-City, JP
Contact	Shogo Nagao
510(k) history	3 submissions · 3 cleared · 2016-2022

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