February 9, 2021

NP Medical Inc
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K203265
Trade/Device Name: nPro Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 26, 2021
Received: January 27, 2021

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Mavadia-shukla -S

For Elizabeth F. Claverie-Williams
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203265

Device Name
nPro Surgical Mask

Indications for Use *(Describe)*

The nPro surgical masks are intended for operating room personnel and other general health care workers to protect both patients and healthcare workers from the transfer of microorganisms, blood and body fluids and particulate materials. nPro Surgical Masks are single use, disposable devices provided non-sterile.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K203265 510(k) Summary

nPro Surgical Mask

Manufacturer: NP Medical Inc.
101 Union Street
Clinton, MA 01510

Contact: Ruthann S. Rapp
101 Union Street
Clinton, MA 01510
Telephone Number: (978) 365-8105
Fax Number: (978) 365-4025

Summary Date: 5 February 2021

Trade Name: nPro Surgical Mask
Model Number: 6409996
Classification Panel: General & Plastic Surgery
Classification/Regulation: Class II per 21CFR878.4040
Regulation Name: Surgical Apparel
Common Name: Surgical Mask
Product Code: FXX
Submission Type: Traditional 510(k)

Predicate Name/510(k): Cardinal Health Insta-Guard® Procedure Mask/K142990

Device Description:

The nPro surgical mask meets ASTM F2100-19 Level 1 performance requirements for bacterial filtration efficiency, differential pressure, sub-micron particulate filtration efficiency, resistance to penetration by synthetic blood and flame spread.

The three-ply pleated mask fabric can be vertically adjusted to cover the user's mouth and nose. The inner and outer layers are constructed of non-woven fabric. The middle layer is constructed of melt-blown negative charge non-woven fabric and includes a flexible nose wire to conform to the user's nose and reduce air gaps. The three layers of the mask body are collated and ultrasonically welded around the edges to enclose the filter media and nose wire. The polyester-spandex ear loops are ultrasonically welded to the mask body. All materials are not made with natural rubber latex. The nPro Surgical Masks are single use, disposable devices that are provided non-sterile in a dispensing carton.

Intended Use and Indication for Use:

The nPro Surgical Masks are intended for operating room personnel and other general healthcare workers to protect both patients and healthcare workers from the transfer of microorganisms, blood and body fluids, and particulate materials. The nPro Surgical Masks are single use, disposable devices provided non-sterile.

Comparison of Technological Characteristics:

The nPro Surgical Mask, model number 6409996 is very similar to the Cardinal Health Insta-Guard® Procedure Mask, model number AT71021, cleared through 510(k) number K142990 with regards to claims, safety, effectiveness, design, performance and intended use. The nPro Surgical Mask is compared to the predicate device in the Table 1 below.

Table 1: Predicate Comparison Table

Element of Comparison	nPro Surgical Mask	Predicate Device Insta-Guard® Procedure Mask (K142990)	Remark
Classification/Regulation	II per 21CFR878.4040	II per 21CFR878.4040	Same
Regulation Name/Panel	Surgical Apparel/ General & Plastic Surgery	Surgical Apparel/General & Plastic Surgery	Same
FDA Product Code	FXX	FXX	Same
Model Number	6409996	AT71021	N/A
OTC Use	Yes	Yes	Same
Intended Use/Indications for Use	The nPro surgical masks are intended for operating room personnel and other general health care workers to protect both patients and healthcare workers from the transfer of microorganisms, blood and body fluids and particulate materials. nPro Surgical Masks are single use, disposable devices provided non-sterile.	Cardinal Health Insta-Guard® Procedure Masks are intended to be worn by operating room personnel and other general health care workers to protect both patients and healthcare workers against the transfer of microorganisms, blood and body fluids, and airborne particulates. Cardinal Health Insta-Guard® Procedure Masks are single use, disposable devices provided non-sterile.	Same
Material Composition			
Outer Facing Layer	Blue non-woven fabric cellulose and polyester	Blue non-woven tissue, cellulose and polyolefin materials	Similar
Middle Layer	Melt blown polypropylene	Non-woven tissue, cellulose, and polyolefin materials	Similar
Inner Facing Layer	White non-woven fabric cellulose and polyester	Non-woven tissue, cellulose and polyolefin materials	Similar
Nose Wire	Polyethylene, Paper, Steel	Nose wire	Similar

Element of Comparison	nPro Surgical Mask	Predicate Device Insta-Guard® Procedure Mask (K142990)	Remark
Ear Loop	Polyester and Spandex, not made with natural rubber latex	Polyester and Spandex, not made with natural rubber latex	Same
Specifications			
Dimensions	6.9 in x 3.7 in (before opening)	7 in x 3.375 in (before opening)	Similar
Layers	3 Layers	3 Layers	Same
Style	Pleated	Pleated	Same
Features	Elastic earloops Malleable nose wire	Elastic earloops Malleable nose wire	Same
Performance	Meets ASTM F2100-19 level 1 requirements	Meets ASTM F2100-11 level 1 requirements	Similar
Manufacturing	Sonically sealed edges and earloops	Sonically sealed edges and earloops	Same
Packaging	50 Masks per carton	50 Masks per carton	Same
Sterilization Method	Provided non-sterile	Provided non-sterile	Same
Use Profile	Single Use	Single Use	Same

The nPro Surgical Mask is as safe, as effective, and performs as well as the predicate device, the Cardinal Health Insta-Guard® Procedure Mask, model number AT71021 in terms of design, materials, intended use, technological characteristics, performance, and materials. The minor differences in material composition, the issue date of the performance standards and size do not pose any concerns related to safety, effectiveness or performance when compared to the predicate device. The nPro Surgical Mask conforms to very similar performance requirements as the predicate device since both products meet ASTM level 1 requirements.

Non-Clinical Testing

Non-clinical tests were conducted to verify that the nPro Surgical Mask met all design specifications and was very similar to the predicate device. A summary of the non-clinical performance requirements, test methods, acceptance criteria, sample size and test results of the nPro Surgical Mask is provided in the table below:

Performance Requirements (units)	Test Method	Acceptance Criteria	Sample Size	Results
Bacterial filtration efficiency (%)	ASTM F2101-19	≥95%	32 each from 3 lots	Pass, 99.1%
Differential pressure (H_2O / cm^2)	EN 14683:2019 (Annex C)	<5.0 mm H_2O / cm^2	32 each from 3 lots	Pass, 4.5 mm H_2O / cm^2
Sub-Micron particulate filtration efficiency (%)	ASTM F2299-03	≥95%	32 each from 3 lots	Pass, 99.4%
Resistance to penetration by synthetic blood (mm Hg)	ASTM F1862-17	≥80 mm Hg (Accept on 3, reject on 4 per lot, AQL=4%)	32 each from 3 lots	Pass 32 out of 32 passed 30 out of 32 passed 32 out of 32 passed
Flammability Class	16 CFR Part 1610	Class 1 Rating	32 each from 3 lots	Pass, Class 1 Rating
Structural Integrity Failure	NP-TM-2019-0188-1	Ear loops must not detach when exposed to a 5N load when tested individually (Accept on 0, reject on 1)	23 each from 3 lots	Pass, Greater than 5N

The materials used in the nPro Surgical Mask device design are shown through testing to meet biocompatibility requirements per ISO 10993-1:2018 based on their level and duration of interaction. The use profile of the device establishes it as having surface contact with intact skin for a prolonged duration. Per FDA guidance, biocompatibility test endpoints for this type of device are defined as cytotoxicity, sensitization and irritation or intracutaneous reactivity. The direct patient contacting materials of the nPro Surgical Mask are the earloops and the inner mask layer, while the entire mask is considered indirect patient contacting. Under the conditions of the study, the test article was found to be non-cytotoxic per ISO 10993-5:2009, non-sensitizing per ISO 10993-10:2013 and non-irritating per ISO 10993-10:2013.

Clinical Tests

No clinical studies were performed for this product.

Conclusion:

The nPro Surgical Mask is as safe, as effective, and performs as well as the predicate device, the Cardinal Health Insta-Guard® Procedure Mask, model number AT71021 in terms of design, materials, intended use, technological characteristics and materials. The minor differences in material composition and size do not pose any concerns related to safety, effectiveness or performance when compared to the predicate device. The nPro Surgical Mask conforms to very similar performance requirements as the predicate device since both products meet ASTM level 1 requirements. The conclusions drawn from the nonclinical tests demonstrate that the nPro Surgical Mask is as safe, as effective and performs as well as the predicate device, the Cardinal Health Insta-Guard® Procedure Mask, model number AT71021, cleared through 510(k) number K142990.