



September 17, 2019

AMD Medicom, Inc.  
Nektaria Markoglou  
Director, Product Innovation and Development  
2555 Chemin de l'Aviation,  
Pointe-Claire  
Montreal, H9P 2Z2 Ca

Re: K190308

Trade/Device Name: Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks (ASTM Level 1), Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks, Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks (ASTM Level 1), Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks (ASTM Level 1)

Regulation Number: 21 CFR 878.4040

Regulation Name: Surgical Apparel

Regulatory Class: Class II

Product Code: OXZ

Dated: February 7, 2019

Received: February 15, 2019

Dear Nektaria Markoglou:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray lii III -S

For Elizabeth Claverie, M.S.  
Assistant Director for THT4B2  
Acting Assistant Director for THT4B1  
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

## Indications for Use

510(k) Number (if known)

K190308

Device Name

Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks (ASTM Level 1), Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks, Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks (ASTM Level 1) and Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks

Indications for Use (Describe)

Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Mask (ASTM Level 1), Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Mask, Medicom SafeMask Premier Pediatric Procedure Earloop Face Mask (ASTM Level 1) and Medicom SafeMask Premier Pediatric Procedure Earloop Face Mask are intended to be worn by the patient/child (recommended 4-12 years of age). The face mask is to be placed on nose and mouth as a protective barrier to provide respiratory protection in procedures or situations where there is a risk of microorganism, body fluid and particulate aerosol transfer. It is a single use, non-sterile disposable device that is recommended for use in healthcare settings with appropriate adult supervision.

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.

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## 510(k) Summary K190308

510(k) Submitter: AMD Medicom Inc.

Address: 2555 Chemin de l'Aviation,  
Pointe-Claire, Québec, H9P 2Z2, Canada

Contact person: Dr. Nektaria Markoglou,  
Director, Product Innovation and Development

Date Prepared: September 16, 2019

Trade Name: Medicom SafeMask Sofskin Pediatric Procedure Earloop Face  
Masks (ASTM Level 1), Medicom SafeMask Sofskin Pediatric  
Procedure Earloop Face Masks, Medicom SafeMask Premier  
Pediatric Procedure Earloop Face Masks (ASTM Level 1) and  
Medicom SafeMask Premier Pediatric Procedure Earloop Face  
Masks

Regulation Number: 21CFR878.4040

Regulation Name: Mask, Surgical

Device Class: Class II

Device Product Code: OXZ

Device Classification Name: Mask, Surgical

Predicate Device: Prestige Ameritech Pediatric Child's Face Mask (K160100)

### Device Description

Medicom Pediatric/Child's Face Mask is a manufactured pleated three-layer mask construction utilizing ultrasonic bonding. The patterned (ink printed) outer layer is composed of spunbound polypropylene (SBPP) material. The filter media is composed of meltblown polypropylene (MBPP). The inner is either tissue/ cellulose or a spunbound polypropylene (SBPP) layer. Bindings are composed of nonwoven polyester and earloops are made of flat elastic knitted polyester band. A malleable polypropylene nosepiece (made of plastic covered iron wire or 100% aluminum piece) is placed within the bindings for comfort and individualized fit around the wearer's nose. Medicom Pediatric/Child's Face Mask is a non-sterile single use disposable device. The device safety of effectiveness is not affected by storage conditions with no shelf life.

## Indication for Use

Prestige Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks (ASTM Level 1), Medicom SafeMask Sofskin Pediatric Procedure Earloop Face Masks, Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks (ASTM Level 1) and Medicom SafeMask Premier Pediatric Procedure Earloop Face Masks are intended to be worn by the patient/child (recommended 4-12 years of age). The face mask is to be placed on nose and mouth as a protective barrier to provide respiratory protection in procedures or situations where there is a risk of microorganism, body fluid and particulate aerosol transfer. It is a single use, non-sterile disposable device that is recommended for use in healthcare settings with appropriate adult supervision.

## Predicate Device

- Ameritech Pediatric Child's Face Mask (K160100)

## Comparison of the Technological Characteristics with the Predicate

The table below compares the construction, technology, design, claims and intended use of Medicom Pediatric/ Child's Face Mask and the predicate device.

| Component Comparison                       | Prestige Ameritech Pediatric/Child's Face Mask (Predicate)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Medicom Pediatric/Child's Face Mask Subject device                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer                               | Prestige Ameritech Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | AMD Medicom Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 510k Number                                | K160100                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | K190308                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Intended Use                               | The Prestige Ameritech Pediatric/Child Face Mask is intended to be worn by patient/child. The Pediatric/Child Facemask is a single use, disposable device, provided non-sterile. The Pediatric/Child Facemask is intended to be worn by the patient (ages 4-12) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. The mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur. | The Medicom Pediatric/Child's Face Mask is intended to be worn by the patient/child (recommended 4-12 years of age). The face mask is to be placed on nose and mouth as a protective barrier to provide respiratory protection in procedures or situations where there is a risk of microorganism, body fluid and particulate aerosol transfer. It is a single use, non-sterile disposable device that is recommended for use in healthcare settings with appropriate adult supervision. |
| Mask Construction & Technological Features | The Prestige Ameritech Pediatric/Child's Face Mask is manufactured using ultrasonic bonding, composed of 3 layers of materials and pleated to form the mask.                                                                                                                                                                                                                                                                                                                                                                                                                                             | Medicom Pediatric/Child's Face Mask is a manufactured pleated three-layer mask construction utilizing ultrasonic bonding. The patterned (ink printed) outer layer is                                                                                                                                                                                                                                                                                                                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| The inner layer is composed of nonwoven, the middle layer is meltblown polypropylene filter material, and the outer layer is cellulose. Decorative patterns are printed with colored inks. Masks are help in place on wearer with knitted polyester/spandex elastic earloop and contain a malleable aluminum nosepiece strip. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across diverse population. The Pediatric/Child Face Mask is a single use, disposable device, provided non-sterile with no shelf-life. Storage conditions will not affect device safety or effectiveness. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex. |                                                          | composed of spunbound polypropylene (SBPP) material. The filter media is composed of meltblown polypropylene (MBPP). The inner is either tissue/cellulose or a spunbound polypropylene (SBPP) layer. Bindings are composed of nonwoven polyester and earloops are made of flat elastic knitted polyester band. A malleable polypropylene nosepiece (made of plastic covered iron wire or 100% aluminum piece) is placed within the bindings for comfort and individualized fit around the wearer's nose. Medicom Pediatric/Child's Face Mask is a non-sterile single use disposable device. The device safety and function is not affected by storage conditions with no shelf life. |                                                                         |
| <b>Non-Clinical Performance Testing</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                          | <b>Prestige Ameritech</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Medicom Pediatric/Child's Face Mask</b>                              |
| <b>ASTM F2100</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                          | <b>Predicate</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Subject device (range of performance based on design variations)</b> |
| <b>Standard</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Title</b>                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |
| ASTM F2299M -03 (2017)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Particulate filtration efficiency (PFE) at 0.1 micron, % | 98%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 98.68 - 99.21%                                                          |
| ASTM F2101-14                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Bacterial filtration efficiency (BFE), %                 | 96.32%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 99.43 - 99.5%                                                           |
| Mil – M369454C, Section 4.4.1.2 & EN 14683, Annx. B                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Differential pressure (dP)                               | 1.74                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 2.89 - 3.12                                                             |
| ASTM F1862M-17                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Resistance to penetration by Synthetic Blood             | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | N/A to @ 80 mm Hg (Level 1)                                             |
| <b>Biocompatibility</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                          | <b>Predicate</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Subject device</b>                                                   |
| <b>Standard</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Title</b>                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |
| ISO 10993-5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Cytotoxicity by MEM elution                              | Criteria met                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Criteria met                                                            |
| ISO 10993-10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Primary Skin irritation                                  | Criteria met                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Criteria met                                                            |
| ISO 10993-10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Dermal Sensitization                                     | Criteria met                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Criteria met                                                            |
| <b>Product Safety Tests</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                          | <b>Predicate</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Subject device</b>                                                   |
| <b>Standard</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Title</b>                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |
| BS EN 71-3:2013+A1:2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Safety of Toys- Part 3: Migration of Certain Elements    | Meet acceptance criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Meet acceptance criteria                                                |

|                                                                                                                                                                                                                                                                                                                                            |                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| CPSC-CH-E1002-08.3<br>16 CFR 1303                                                                                                                                                                                                                                                                                                          | Total Lead (Pb) content<br>in non-metal Children's<br>Products                    | Meet acceptance criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | (≤ 20 ppm)<br>Meet acceptance criteria |
| CPSC-CH-E1001-08.3                                                                                                                                                                                                                                                                                                                         | Total Lead (Pb) content<br>in metal Children's<br>Products                        | Meet acceptance criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | (≤ 40 ppm)<br>Meet acceptance criteria |
| CPSC-CH-C1001-09.3<br>16 CFR part 1307                                                                                                                                                                                                                                                                                                     | Analysis of Phthalates<br>(DBP, DEHP, DINP,<br>BBP, DNOP<br>and DIDP)             | Meet acceptance criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | (≤ 50 ppm)<br>Meet acceptance criteria |
| 16 CFR 1500.48, 49, 51-<br>53<br>ISO 17025                                                                                                                                                                                                                                                                                                 | Mechanical Hazards:<br>sharp points, sharp<br>edges and small parts<br>substances | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Meet acceptance criteria               |
| 16 CFR 1500.44                                                                                                                                                                                                                                                                                                                             | Flammability                                                                      | Class 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Class 1                                |
| <b>Anthropometry Study</b>                                                                                                                                                                                                                                                                                                                 |                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                        |
| <b>Predicate</b>                                                                                                                                                                                                                                                                                                                           |                                                                                   | <b>Subject device</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                        |
| Based on an anthropometric study sample that is representative of the current US population in both gender and racial distribution, the Prestige Ameritech Pediatric/Child's Face Mask will provide adequate coverage to children between the ages of 4-12 years old, of weight between 24-153 pounds and of height between 3'3" and 5'4". |                                                                                   | The Medicom Pediatric/Child's Face Mask was evaluated based on anthropometry study on children aged 4-12 years old. The participants ranged from 84.8 cm (33.4 inches) – 170.2 cm (67 inches) in height and 16.3 kg (35.94 pounds) – 76.7 kg (169.1 pounds) in weight. Medicom Pediatric/Child's Face Mask provides adequate coverage to children 4-12 years old based on proper adult supervision and assurance that mask fits correctly on the child's face (by sitting on the bridge of the nose and it is secured under chin, by not impeding vision by covering the eyes, not pulling at the ears and ensuring child is breathing normally while wearing the masks. |                                        |
| <b>Sterility and Use</b>                                                                                                                                                                                                                                                                                                                   | <b>Predicate</b>                                                                  | <b>Subject device</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                        |
|                                                                                                                                                                                                                                                                                                                                            | Single use, non-sterile                                                           | Single use, non-sterile device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                        |

**Abbreviation:** N/A: Not Applicable

#### Conclusion:

The conclusion drawn from the non-clinical tests performed (discussed above) demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.