



April 12, 2024

Tosama, d.o.o.  
Janez Obreza  
Regulatory Affairs Manager  
Vir, Saranoviceva cesta 35  
Domžale, Slovenia 1230  
SLOVENIA

Re: K232060  
Trade/Device Name: TOSAMA Reusable Applicator  
Regulation Number: 21 CFR 884.5470  
Regulation Name: Unscented Menstrual Tampon  
Regulatory Class: II  
Product Code: HEB, HIL  
Dated: July 10, 2023  
Received: March 12, 2024

Dear Janez Obreza:

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 (the 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 available 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

  
Reginald K. Avery -S

*for* Jason R. Roberts, Ph.D.

Assistant Director  
DHT3B: Division of Reproductive,  
Gynecology and Urology Devices  
OHT3: Office of Gastrorenal, ObGyn,  
General Hospital, and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K232060

Device Name

TOSAMA Reusable Applicator

Indications for Use (Describe)

The TOSAMA Reusable Applicator is intended to be used to insert a digital (no applicator) menstrual tampon into the vagina.

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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## 510(k) Summary

**K232060**

### 1. Contact Details

Applicant Name: Tosama, d.o.o.  
Applicant Address: Vir, Šaranovičeva cesta 35, Domžale 1230, Slovenia  
Applicant Contact Telephone: 386-1-7290155  
Applicant Contact: Janez Obreza  
Applicant Contact Email: [janez.obreza@tosama.si](mailto:janez.obreza@tosama.si)  
Summary Preparation Date: April 12, 2024

### 2. Device Name

Device Trade Name: TOSAMA Reusable Applicator  
Common Name: Reusable Tampon Applicator  
Regulation Name: Unscented Menstrual Tampon  
Regulation Number: 21 CFR 884.5470  
Product Code: HEB (Tampon, Menstrual, Unscented), HIL (Tampon, Menstrual, Scented, Deodorized)  
Regulatory Class: II

### 3. Legally Marketed Predicate Devices

Predicate 510(k) Number: K212479  
Predicate Trade Name: COHITECH Reusable Tampon Applicator  
Company Name: Cotton High Tech S.L.

The predicate device has not been subject to a design-related recall.

### 4. Device Description

The TOSAMA Reusable Applicator is a non-sterile, single user, reusable medical device. It is intended to be sold in three different packaging configurations: Applicator only, Applicator with prepackaged tampons (regular, super and super plus absorbency versions) and Applicator with loose tampons of super and regular absorbency. The device is comprised of a tampon holder and pusher made of thermoplastic elastomer and a lipstick-style cap to protect the applicator, which is made of polystyrene. The tampon holder and pusher are connected at the hinged base of the holder, which opens to load a tampon and closes to allow the pusher to eject a tampon. The holder and pusher are designed to stay connected and not separate during use, storage, or cleaning. The TOSAMA Reusable Applicator requires the user to load the applicator with a legally marketed menstrual tampon. The use-life of the subject TOSAMA Reusable Applicator is 2 years. The device requires the user to clean (holder and pusher) and disinfect (lipstick cap) before initial use, before long term storage and at the end of the menstrual cycle, as well as to clean the device after each use. The applicator is available in one size for all sizes of tampon absorbencies (Light, Regular, Super and Super Plus) and accommodates a maximal tampon diameter of 15 mm. The holder inner diameter is  $8.2 + 0.25/- 0.10$  mm, pusher length is  $83.7 \pm 0.5$  mm and total length and

diameter of the applicator (without the lipstick cap) is  $70.8 \pm 1.0$  mm and  $19.6 \pm 0.05$  mm respectively.

## 5. Indications for Use

The TOSAMA Reusable Applicator is intended to be used to insert a digital (no applicator) menstrual tampon into the vagina.

## 6. Comparison of Technological Characteristics and Indications for Use

Description	Subject Device	Predicate Device
<b>Device name</b>	TOSAMA Reusable Applicator	COHITECH Reusable Tampon Applicator
<b>Manufacturer/Applicant</b>	Tosama, d.o.o	Cotton High Tech, S.L.
<b>510(K) Number</b>	K232060	K212479
<b>Product code</b>	HEB, HIL	HEB, HIL
<b>Regulation Number</b>	884.5470	884.5470
<b>Material Composition</b>	Polystyrene, thermoplastic elastomer	Polyethylene, polypropylene
<b>Indications for use</b>	The TOSAMA Reusable Applicator is intended to be used to insert a digital (no applicator) menstrual tampon into the vagina.	COHITECH Reusable Tampon Applicator is intended to be used to insert a digital menstrual tampon into the vagina.
<b>Usability</b>	Reusable	Reusable
<b>Use- Life</b>	2 years	4 years
<b>Tampon Compatibility</b>	Digital tampons of various sizes (regular, super, and super plus)	Digital tampons of various sizes (regular, super, and super plus)
<b>Device Design</b>	Holder, pusher, and a Lipstick cap for holder. Holder has hinged cap to facilitate tampon loading	Outer tampon housing and inner pusher and storage case

The subject and predicate device have the same intended use – to deliver digital menstrual tampons into the vagina. The subject device differs from the predicate device in technological characteristics. The subject device has a different device design, use-life, and material composition. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

## 7. Summary Discussion of Non-Clinical Performance Testing

### Biocompatibility:

The following biocompatibility studies were performed on the Subject device in accordance with the requirements of ISO 10993-1:2018 “*Biological evaluation of medical devices – Part 1:*

*Evaluation and testing within a risk management process, ISO 14971:2019 Medical devices- Application of risk management to medical devices, and the 2023 FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (Delayed Hypersensitivity) (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-23:2021)

The results showed that the subject device was non-cytotoxic, non-irritating, and a non-sensitizer.

#### Bench Testing:

The following performance characteristics were assessed to demonstrate that the proposed subject device met applicable design and performance requirements:

- Device weight
- Physical dimensions
- Functional evaluation, including:
  - Ejection force of tampon
  - Force required to pull plunger from applicator.
  - Pusher Stability
  - Hinge durability over use life
  - Lipstick cap compatibility over use life
- Use-life testing

The results of the non-clinical performance data were acceptable and met the established acceptance criteria.

#### Reprocessing, Cleaning, and Disinfecting

The cleaning instructions were developed per the recommendations in the 2015 FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*" The TOSAMA Reusable Applicator (Holder and Pusher) should be washed with warm water and mild soap after every use and boiled and disinfected before the first use and at the end of each menstrual cycle. The applicator Lipstick Cap should be disinfected with alcohol (ethanol or isopropyl alcohol) after every menstrual cycle.

The TOSAMA Reusable Applicator is not provided sterile and is not intended to be sterilized by users.

### **8. Conclusion:**

The subject and predicate device have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The results of the non-clinical testing described above demonstrate that TOSAMA Reusable Applicator is substantially equivalent to the predicate device.