510(k) Summary

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Device Trade Name: re.t.a™ Reusable Tampon Applicator

Common Name: Reusable Tampon Applicator

Classification: Class: II
Panel: Obstetrics/Gynecology
Regulation: 884.5470, Unscented Menstrual Tampon
Product Code: HEB (Unscented Menstrual Tampon) and HIL (Scented-Deodorized Menstrual Tampon)

Predicate Device: K091749, U by Kotex® Click® Unscented Menstrual Tampons

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

Device Description:

The re.t.a.™ Reusable Tampon Applicator is a non-sterile, single user reusable device. It is intended to be sold on its own, without a pre-loaded tampon. The applicator requires the user to insert a legally-marketed digital/non-applicator menstrual tampon into the applicator at the time of use. The use-life of the subject applicator is two years.

Indications for Use Statement:

The re.t.a.™ reusable tampon applicator in intended to be used to insert a digital menstrual tampon into the vagina.

Comparison of Technological Characteristics and Indication for Use:

The following table compares the indications for use statement of the subject and predicate device.

Device & Predicate Device(s):	K180850	K091749
Indication for Use	The re.t.a.TM reusable tampon applicator in intended to be used to insert a digital menstrual tampon into the vagina	Kimberly-clark U by Kotex is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid
Usability	Reusable	Single use
Use-life	2 years	N/A
Tampon compatibility	Digital tampons of various sizes	Kotex Click (applicator specific tampon)
Device Design	Sleeve with slit, pusher, and outer cover	Sleeve with compressed tampon, pusher and outer cover

The Indications for Use statement for the subject device is different from the predicate device. However, they have the same intended use because the subject applicator is an accessory to a class II tampon device.

The subject device differs from the predicate device in technological characteristics. The predicate device is a tampon with applicator whereas the subject device is used for the placement of digital tampons. The subject device is similar in its operating principle (applicator portion of the predicate device). On the other hand, there are several design, usability, and tampon compatibility differences between the subject device and predicate device.

These differences do not raise different questions of safety or effectiveness.

Performance Data

The following tests demonstrate that the proposed subject devices met the applicable design and performance requirements:

- Functional evaluation, including assessment of:
  - Weight
  - Physical dimensions
  - Outer cover uncap-force
  - Tampon compatibility testing
  - Ejection force
- Use-life testing
- Biocompatibility including cytotoxicity, vaginal irritation, and sensitization testing
- Cleaning Validation

Conclusion

The subject device is substantially equivalent to the predicate device.