510K Summary
K181844

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Date Prepared:	April 12, 2019
Device Trade Name:	One Touch
Device Common Name:	Male Natural Rubber Latex Condom
Regulation Name:	Condom
Regulation Number:	884.5300
Product Code:	HIS (Condom)
Regulatory Class:	Class II
Predicate Device:	K081265: Thai Nippon Male Latex Condom 56 mm (nominal width), flared, colorless, silicone lubricated The predicate device has not been subject to a design-related recall

Device Description:
The One Touch condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitting membrane. The condom is straight-walled with a

reservoir tip, and is silicone lubricated. Condom dimensions are length 210 ± 10 mm, width 60 ± 2 mm, and thickness 0.07 ± 0.01 mm. The condom is designed to conform to the requirements of ASTM D3492:2016 and ISO 4074:2015.

Indications for Use:

The One Touch male natural rubber latex condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Substantial Equivalence Comparison

Characteristic	**Subject Device K181844**	**Predicate Device K081265**	**Comparison**
Indications for Use	The One Touch male natural rubber latex condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	The Thai Nippon Male Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and transmission of sexually transmitted diseases).	**Same**: Although there are minor wording differences, the indications for use and intended uses are the same.
Condom Material	Natural Rubber Latex	Same	**Same**
Design	Straight-walled, smooth, reservoir tip	Straight-walled, flared at closed end, reservoir tip	**Different**: The subject device is a standard straight-walled condom, while the predicate has a flared closed end. This difference does not raise different questions of Safety and Effectiveness (S&E).
Colors	None	None	**Same**
Lubricant	Silicone lubricant	Same	**Same**
Dusting Agent	Corn Starch	Corn Starch	**Same**
Nominal Length	210 mm ± 10mm	200 mm	**Different:** The subject device is slightly longer than the predicate device. However, this difference does not raise different questions of S&E. The length is within the

			range specified in ASTM D3492-16.
Nominal Width	60 mm ± 2mm	56 mm	**Different:** The subject device is slightly wider than the predicate device. However, this difference does not raise different questions of S&E. The width is within the range specified in ASTM D3492-16 and ISO 4074:2015.
Nominal Thickness	0.07 ± 0.01 mm	0.07 mm	**Same**

As shown above, there are minor differences in the wording of the subject and predicate device indications statements; however, the intended uses are the same. Regarding technological characteristics, the subject and predicate devices have similarities in condom material, lubricant type, and lack of colorants. However, differences do exist as described in the table above (e.g., dimensions, general design, etc.). The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

Summary of Performance Testing:

- Biocompatibility testing as follows:
  - Cytotoxicity testing per ISO 10993-5:2009
  - Guinea pig maximization sensitization testing per ISO 10993-10:2010
  - Vaginal irritation testing per ISO 10993-10:2010
  - Acute systemic toxicity testing for ISO 10993-11:2006

- Physical Testing Data: Three lots of devices were tested at baseline and met airburst specifications of ISO 4074:2015 – Natural rubber latex male condoms – Requirements and test methods and ASTM D3492:2016 – Standard Specification for Rubber Contraceptives (Male Condoms).

- Shelf Life: Stability testing to support a shelf-life of five years per the requirements of 21 CFR §801.435.

Conclusion:
Based on the results of the testing and safety data described above, the One Touch male natural rubber latex condom is as safe and effective as the predicate device. The performance data support a determination of substantial equivalence.