510(k) SUMMARY

Date of Summary: September 26, 2017

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Proprietary/Trade Name: JUD custom fit condom
Common Name: Male Latex Condom
Classification Name: Condom

Device Classification Class II per 21 CFR §884.5300
Product Code HIS, Condom

Predicate Device They Fit Condom K150072
Reference Device They Fit Condom K122219

The predicate and reference devices have not been subject to a design-related recall.

Device Description:

The JUD custom fit condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The condom is shaped with a reservoir end and is flat with a cylindrical shape. JUD custom fit condoms are available in 23 sizes of different length/width combinations. There is a fitting kit and instructions included as part of safe and effective usage of the condom.

JUD custom fit condoms are provided pre-lubricated with a silicone-based lubricant. JUD custom fit condoms are not provided with spermicide, and contain no flavors or color additives. The user must use a fitting kit to select the appropriate size of the JUD custom fit condom.

Indications for Use

The JUD custom fit condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

	SIZE CODE	LENGTH (mm)	WIDTH (mm)
1.	54W	130	45
2.	54E	130	47
3.	54J	130	51
4.	36J	150	51
5.	75J	173	51
6.	54M	130	49
7.	36M	150	49
8.	54N	130	57
9.	36N	150	57
10.	75N	173	57
11.	29N	199	57

	SIZE CODE	LENGTH (mm)	WIDTH (mm)
12.	36P	150	60
13.	75P	173	60
14.	29P	199	60
15.	75R	173	64
16.	29R	199	64
17.	54S	130	53
18.	36S	150	53
19.	75S	173	53
20.	54U	130	55
21.	36U	150	55
22.	75U	173	55
23.	29U	199	55

Comparison of Technological Characteristics

Characteristic	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	Jud custom fit condom	They Fit Condom	They Fit Condom	N/A
510(k) Number	K172414	K150072	K122219	N/A
Common Name	Male Latex Condom	Male Latex Condom	Male Latex Condom	N/A
Manufacturer	Richter Rubber Technology, Sdn. Bhd. Plot 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Malaysia	They Fit Condom Michael Cecil, MD 4140 Tate Street Covington, GA 30014	They Fit Condom Michael Cecil, MD 4140 Tate Street Covington, GA 30014	N/A
Indications for Use	The JUD custom fit condom is used for contraception and for prophylactic purposes (to help	The condom is used for contraception and for prophylactic purposes to help	The condom is used for contraception and for prophylactic purposes (to help	Same

	prevent pregnancy and the transmission of sexually transmitted diseases).	prevent pregnancy and the transmission of sexually transmitted diseases.	prevent pregnancy and the transmission of sexually transmitted diseases).	
Size(s)	Varied sizes with different length/width combinations.	Varied sizes with different length/width combinations.	Varied sizes with different length/width combinations.	Same
Length	130mm, 150mm, 173mm, 199mm	123mm, 133mm, 143mm, 153mm	163mm, 178mm, 193mm, 208mm	Different; subject device lengths fall within the range of the predicate and reference devices.
Width	45 mm, 47mm, 49mm, 51mm, 53mm, 55mm, 57mm, 60mm, 64mm	45mm, 47mm, 49mm, 51mm, 53mm, 57mm, 60mm, 64mm	49mm, 51mm, 53mm, 55mm, 57mm, 60mm, 64mm	Same
Reservoir tip	yes	yes	yes	Same
Single use device	yes	yes	yes	Same
Natural Latex	yes	yes	yes	Same

The principle of operation of the JUD custom fit condoms, placing condom on erect penis before sexual contact to avoid transmission of bodily fluid and infectious organisms within, is identical to predicate. As noted in the table above, JUD custom fit condoms have the same indications for use and basic technological characteristics as the predicate and reference condoms. The JUD custom fit condoms are made of natural rubber latex, are prelubricated, and have similar sizes to the predicate. The JUD custom fit condom dimensions fall within the range of sizes of the predicate and reference devices, though they are offered in different size configurations. The difference in available sizes of the JUD custom fit condoms does not raise different questions of safety and effectiveness.

Nonclinical Testing Summary

Bench testing

Dimensional tests, burst volume and pressure tests, and freedom from holes and visible defects tests have been conducted per WHO 2010 and ISO 4074:2015. Package seal integrity test has been conducted per ISO 4074:2015. The dimensions and burst volume and pressure of the condoms tested conform to the aforementioned standards. There were no visible defects or damaged package seal identified in the tested samples.

Description	**Summary and Conclusion**
Dimensional	ISO 4074: Acceptance criteria met
Lubricant quantity	ISO 4074: Acceptance criteria met
Burst Volume and Pressure	ISO 4074: Acceptance criteria met
Freedom from Holes and Visible Defects	ISO 4074: Acceptance criteria met
Package Seal Integrity	ISO 4074: Acceptance criteria met

Shelf Life

The JUD custom fit condom has a shelf-life of 5 years. The results of shelf life testing show that each condom variant maintained its specifications for the proposed shelf-life.

Biocompatibility

The JUD custom fit condom is considered a surface contacting device of category A – limited contact of <24 hours on intact skin/mucosal membrane. The skin contacting component is the latex condom itself made from natural latex rubber. These condoms contain no flavors or color additives.

The following biocompatibility testing was conducted on the JUD custom fit condom:

Biological Endpoint	**Description**	**ISO Standard**	**Results**	**Test article**
Cytotoxicity	In-vitro cytotoxicity using the direct contact method	ISO 10993-5:2009	No cytotoxic reactivity was found	Identical to finished devices*
Acute systemic toxicity	Systemic toxicity in Swiss albino mice	ISO 10993-11:2006	There was no mortality or evidence of systemic toxicity resulted from the test article extract.	Identical to finished devices
Vaginal irritation	Vaginal irritation in rabbits	ISO 10993-10:2010	The test article was found to be non-irritating, i.e., did not show any signs of vaginal irritation.	Identical to finished devices
Skin	Skin sensitization	ISO 10993-	The test article	Identical to

sensitization	(maximization) test in Guinea Pigs	10:2010	extract did not induce skin sensitization.	finished devices

*The test article utilized for the biocompatibility testing was a single condom variant. All JUD custom fit condoms undergo the same manufacturing process, have the same chemical, physical, and surface properties, and have the same ratio of component materials as the test article.

Substantial Equivalence Conclusion

The subject device is identical to the predicate devices in intended use. The subject device, predicate and reference devices are constructed out of the same materials (natural rubber latex), and have the same basic technological characteristics. The subject device dimensions fall within those of the predicate and reference devices, though the subject device has slightly different size configurations. Both the subject device and predicate devices conform to the same standards for performance specifications. Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The non-clinical testing conducted on the subject device, including dimensional testing, lubricant quantity, burst volume and pressure testing, freedom from holes and visible defects testing, package seal integrity, shelf life, cytotoxicity, acute systemic toxicity, vaginal irritation and skin sensitization demonstrate that the subject device is as safe and effective as the predicate. Therefore, the JUD custom fit condom is substantially equivalent to the predicate, TheyFit.