510(k) SUMMARY:

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Date Prepared:	January 15, 2018
Device Trade Name:	Trojan™ Chain Reaction Natural Rubber Latex Condom With Sensate Lubricant
Device Common Name:	Natural Rubber Latex Condom
Product Code:	HIS (condom)
Regulatory Class:	Class II
Classification Name:	Condom (21 CFR § 884.5300)
Predicate Device:	K131887: TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant The predicate device has not been subject to a design related recall.

Description of Device:
The Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant is made of a natural rubber latex sheath, which completely covers the penis with a fitted membrane and has a silicone-based lubricant containing low levels of sensory ingredients applied directly to the condom to create a perception of warming, cooling, and/or tingling. The condom is a bulbous shaped condom with 11 rows of continuous ribs on the shaft and 9 rows of continuous ribs on the bulb. The Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant meets the specifications of ASTM D3492-16. The condom has a nominal length of 185 mm and a nominal flat-width of 54 mm, measured 30 mm from the open end. The bulbous portion at the closed end of the condom has a flat-width of 65 mm.

Intended Use of the Device:
The Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant is used for contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).

Predicate Device Comparison:
The subject and predicate device have the same intended use. The subject and predicate device are similar in natural rubber latex formulation, design and dimensions but differ in the formulation of their lubricant systems. This difference in technological characteristics does not raise different questions of safety and effectiveness.

Summary of Performance Testing:
Biocompatibility:
Biocompatibility testing was performed on the Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant in accordance with ISO 10993-1:2009, Biological Evaluation of Medical Devices.

Test Performed	ISO Standard
Cytotoxicity ISO Elution Method	ISO 10993-5
Rabbit Vaginal Irritation	ISO 10993-10
Rabbit Penile Irritation	ISO 10993-10
Primary Rabbit Skin Irritation	ISO 10993-10
Guinea Pig Maximization Sensitization	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11

The results of testing demonstrate that the subject device is biocompatible.

Physical Testing Data:
Three (3) lots of Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant were tested at baseline and met airburst specifications of ASTM D3492-16 Standard Specifications for Rubber Contraceptives (Male Condoms).

Shelf Life:
Stability of the Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant was established from results of physical testing data using a protocol that followed 21 CFR §801.435 as a guide. Based on the evaluation of the results of the physical testing data, the expiration date has been initially set at 36 months and will be then verified through real-time stability through five (5) years in compliance with FDA expiration labeling requirements in 21 CFR §801.435.

Conclusion:
Based on the results of the testing and safety data described above, the Trojan™ Chain Reaction Natural Rubber Latex Condom with Sensate Lubricant is as safe and effective as the predicate device. The performance data support a determination of substantial equivalence.