



Food and Drug Administration
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October 20, 2016

Guangzhou Daming United Rubber Products Ltd.
Yongbing Xie
Chairman Secretary
No. 1 Daming Street, Port Industrial Zone Huada District
Guangzhou, Guangdong 510802
CHINA

Re: K153016
Trade/Device Name: aoni Natural Rubber Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
Dated: August 17, 2016
Received: September 21, 2016

Dear Yongbing Xie:

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 (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. 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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153016

Device Name
aoni Natural Rubber Latex Condom [Smooth/Dotted/Combined]

Indications for Use (Describe)

aoni Natural Rubber Latex Condom [Smooth/Dotted/Combined]

- a) Smooth 52mm/54mm/55mm natural
- b) Dotted 52mm natural
- c) Combined [smooth+girdling] 52mm natural
- d) Combined [dotted+girdling] 52mm natural

The Condom is used for contraception and for prophylactic purpose (to help prevent pregnancy and the transmission of sexually transmitted infections.)

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 K153016

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Contact Person: Yongbing Xie

Date Prepared: 20 October, 2016

Proprietary Name: aoni Natural Rubber Latex Condom

Common Name: Condom

Classification Name: Condom (21 CFR §884.5300)

Product Code: HIS – Condom_

Classification: Class II

Predicate Device: LifeStyles Zero Lubricated Latex Condom
510(k) # K120394
Predicate has not been subject to a design-related recall

Description of the Device: aoni Natural Rubber Latex Condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. These condoms conform to ISO 4074:2002 Natural Rubber Latex Condoms – Requirements and Test Methods, ASTM D3492-14 Standard Specification for Rubber Contraceptives (Male Condom), and ISO 10993-1 Biological Evaluation of Medical Devices – Part 1(2009).

These condoms have repeated contact potential for a duration of <24 hours and contact the mucosal membrane. They are for home use.

aoni Natural Rubber Latex Condom include four types as following:

[Smooth]: aoni Natural rubber latex condom [Smooth] are straight walled bulbous ended with smooth surface, having a nominal length of 180mm, a nominal width of 52mm/54mm/55mm, a nominal thickness of 0.036-0.080mm, Natural color

[Dotted]: aoni Natural rubber latex condom [Dotted] are straight walled bulbous ended with Dotted surface, having a nominal length of 180mm, a nominal width of 52mm, a nominal thickness of 0.036-0.080mm, Natural color.

[Combined: (smooth+girdling)]: aoni Natural rubber latex condom [Combined: (smooth+girdling)] are girdling walled bulbous ended with smooth surface, having a nominal length of 180mm, a nominal width of 52mm, a nominal thickness of 0.036-0.080mm, Natural color.

[Combined: (dotted+girdling)]: aoni Natural rubber latex condom

[Combined: (dotted+girdling)] are girdling walled bulbous ended with dotted surface, having a nominal length of 180mm, a nominal width of 52mm, a nominal thickness of 0.036-0.080mm, Natural color.

Intended Use of the Device: This condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections.)

Technological Characteristics

The condom is substantially equivalent to the predicate device, the Latex lubricated condom (K120394).

The indication for use statement for aoni Natural Rubber Latex Condom is consistent with the Latex lubricated condom (K120394), additionally, the design is in conformance with ASTM Latex Condom Standard D3492, and that the condom is made of natural rubber latex. The only differences between our condom and predicate condom (K120394) is condom dimensions, type of lubricant, and fragrance.

Predicate Product Comparison

Table 1 Predicate Product Comparisons - aoni Natural rubber latex condom [Smooth]

Parameters	Guangzhou Daming United Rubber Products Ltd.	Ansell Healthcare Product, LLC
510(k) Number	-	K120394
Intended Use	aoni Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections.)	LifeStyles Zero Condoms is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)
Material	Natural rubber latex	Natural rubber latex
Design	Straight-walled, smooth, cylindrical, reservoir	Straight-walled, cylindrical, reservoir
Nominal Length	180mm	185mm
Nominal width	52mm , 54mm , 55mm	51mm
Nominal thickness	0.036-0.080mm	0.04mm
Color	Natural	Natural
Scented	Yes	No
Lubricant	Water-based lubricant	Silicone (silicone oil)
Biocompatibility	ISO 10993 Acceptance criteria met	ISO 10993 Acceptance criteria met

Table 2 Predicate Product Comparisons - aoni Natural rubber latex condom [Dotted]

Parameters	Guangzhou Daming United Rubber Products Ltd.	Ansell Healthcare Product, LLC

510(k) Number	-	K120394
Intended Use	aoni Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections.)	LifeStyles Zero Condoms is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)
Material	Natural rubber latex	Natural rubber latex
Design	Straight-walled, dotted, cylindrical, reservoir	Straight-walled, cylindrical, reservoir
Nominal Length	180mm	185mm
Nominal width	52mm	51mm
Nominal thickness	0.036-0.080mm	0.04mm
Color	Natural	Natural
Scented	Yes	No
Lubricant	Water-based lubricant	Silicone (silicone oil)
Biocompatibility	ISO 10993 Acceptance criteria met	ISO 10993 Acceptance criteria met

Table 3 Predicate Product Comparisons - aoni Natural rubber latex condom [Combined: smooth+girdling]

Parameters	Guangzhou Daming United Rubber Products Ltd.	Ansell Healthcare Product, LLC
510(k) Number	-	K120394
Intended Use	aoni Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections.)	LifeStyles Zero Condoms is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)
Material	Natural rubber latex	Natural rubber latex
Design	Straight-walled with girdling, smooth, reservoir	Straight-walled, cylindrical, reservoir
Nominal Length	180mm	185mm
Nominal width	52mm	51mm
Nominal thickness	0.036-0.080mm	0.04mm
Color	Natural	Natural
Scented	Yes	No

Lubricant	Water-based lubricant	Silicone (silicone oil)
Biocompatibility	ISO 10993 Acceptance criteria met	ISO 10993 Acceptance criteria met

Table 4 Predicate Product Comparisons - aoni Natural rubber latex condom [Combined:
dotted+girdling]

Parameters	Guangzhou Daming United Rubber Products Ltd.	Ansell Healthcare Product, LLC
510(k) Number	-	K120394
Intended Use	aoni Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections.)	LifeStyles Zero Condoms is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)
Material	Natural rubber latex	Natural rubber latex
Design	Straight-walled with girdling, dotted, reservoir	Straight-walled, cylindrical, reservoir
Nominal Length	180mm	185mm
Nominal width	52mm	51mm
Nominal thickness	0.036-0.080mm	0.04mm
Color	Natural	Natural
Scented	Yes	No
Lubricant	Water-based lubricant	Silicone (silicone oil)
Biocompatibility	ISO 10993 Acceptance criteria met	ISO 10993 Acceptance criteria met

Non-clinical testing:

Biocompatibility : Biocompatibility testing was performed to evaluate the biocompatibility of the aoni Natural Rubber Latex Condom in accordance with ISO 10993-1:2009, the device passed each biocompatibility test identified below:

- Cytotoxicity testing in according to ISO 10993-5:2009
- Skin irritation testing in according to ISO 10993-10:2010
- Vaginal irritation testing in according to ISO 10993-10:2010
- Sensitization testing in according to ISO 10993-10:2010
- Acute systemic toxicity testing in according to ISO 10993-11:2006

Performance testing: Each variant of aoni Natural Rubber Latex Condom was tested and met the specifications of ISO 4074: Natural Rubber Latex Condoms – Requirements and Test Methods, ASTM D3492-14 Standard Specification for Rubber Contraceptives (Male Condom),

Shelf life:

aoni Natural Rubber Latex Condom has a five years (60 month) shelf life based on the results of real time storage and testing of 21 CFR 801.435 and ISO 4074:2012.

Conclusion:

The aoni Natural Rubber Latex Condom is substantially equivalent to the predicate device in indications for use, materials. Safety and performance testing to ASTM D3492-14 Standard Specifications for Rubber Contraceptives (Male Condoms) and ISO 10993 Biological Evaluation of Medical Devices has concluded that the aoni Natural Rubber Latex Condom are substantially equivalent to the predicate devices (K120394) in term of safety and effectiveness.