K122219

510(k) Summary

SEP 27 2013

THEYFIT®

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE:	September 24, 2013
APPLICANT:	TheyFit Michael Cecil, MD 4140 Tate Street Covington, GA 30014 Tel: 404-441-4435 Email: mpcecil@earthlink.net
OFFICIAL CORRESPONDENT:	Penny Northcutt, RAC, FRAPS, CQA Regulatory Consultant for TheyFit REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 Email: pennynorthcutt@theregsolutions.com
TRADE NAME:	TheyFit Male Condom
CLASSIFICATION NAME:	Condom
COMMON OR USUAL NAME:	Condom
DEVICE CLASSIFICATION AND PRODUCT CODE:	Class II per 21 CFR §884.5300 Obstetrics/Gynecology Product Code: HIS
PREDICATE DEVICE NAME:	Karex Large and Extra Large Natural Rubber Latex Condoms, K113061 Karex Male Natural Rubber Latex Condom, K081886

DESCRIPTION OF THE DEVICE:
The TheyFit Male 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. TheyFit condoms are available in 22 sizes, of different length/width combinations.

TheyFit Condoms are provided pre-lubricated with a silicone-based lubricant. TheyFit condoms are not provided with spermicide. The user must use a fitting kit (FitKit) to select the appropriate size TheyFit Condom.

The sizes available are as follows:

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TheyFit Male Condom Model Number Chart		
O77	N17	Z22
O88	N21	Z21
O99	N22	
O11	N77	
O17	D11	
O21	D17	
O22	D21	
N88	D22	
N99	Z11	
N11	Z17	

Legend

Condom Length	Condom Lay Flat Width
O = 163mm	77 = 49mm
N = 178mm	88 = 51mm
D = 193mm	99 = 53mm
Z = 208mm	11 = 55mm
	17 = 57mm
	21 = 60mm
	22 = 64mm

INTENDED USE/INDICATIONS FOR USE:
The subject and predicate device have the same Indications for Use statement, which is, "The TheyFit Male Condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections)."

TECHNOLOGICAL CHARACTERISTICS:
The subject and predicate devices have different technological characteristics. The different technological characteristics of the subject device include its available size range compared to the predicate device and the inclusion of a fitting kit to help the user select his condom size. These different characteristics of the subject device could affect safety and effectiveness, (e.g., clinical slippage and breakage rates and selection of an appropriate condom size). However, the different technological characteristics of the subject device do not raise new types of safety and effectiveness questions because FDA has cleared condoms with different characteristics than previously cleared male condoms that could affect condom failure rates, including new condom material, size, and performance claims (e.g., extra strength).

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PERFORMANCE DATA:

Description	Summary and Conclusion
Biocompatibility	The TheyFit Condoms are identical with regard to material composition and manufacturing process as the predicate device. Therefore, biocompatibility testing completed on the predicate device was leveraged to support the biocompatibility of the TheyFit Condoms.
Airburst	ASTM D3492-08 and ISO 4074:2002 Acceptance criteria met
Water Leak	ASTM D3492-08 and ISO 4074:2002 Acceptance criteria met
Freedom from Holes	ASTM D3492-08 and ISO 4074:2002 Acceptance criteria met
Dimensional Analysis	ASTM D3492-08 and ISO 4074:2002 Acceptance criteria met
Clinical Performance	Clinical performance data was provided for sizes O77-Z22 via a published clinical study (Reece M, Herbenick D, Sanders SA et al, Breakage, slippage and acceptability outcomes of a condom fitted to penile dimensions. Sex Transm Infect 2008; 84(2):143-149.)

CONCLUSION:
The TheyFit Male Condoms (sizes O77-Z22) are substantially equivalent to their proposed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

TheyFit
% Penny Northcutt, RAC, FRAPS, CQA
Executive Director
REGSolutions, LLC
717 Lakeglen Drive
Suwanee, GA 30024

Re: K122219
Trade/Device Name: TheyFit Male Condom (sizes O77-Z22)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
Dated: September 19, 2013
Received: September 20, 2013

Dear Penny Northcutt:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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): K122219

Device Name: **TheyFit Male Condom**

Indications For Use:

The TheyFit male condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

TheyFit Male Condom Model Number Chart		
O77	N17	Z22
O88	N21	Z21
O99	N22	
O11	N77	
O17	D11	
O21	D17	
O22	D21	
N88	D22	
N99	Z11	
N11	Z17	

Legend

Condom Length	Condom Lay Flat Width
O = 165mm	77 = 49mm
N = 180mm	88 = 51mm
D = 195mm	99 = 53mm
Z = 210mm	11 = 55mm
	17 = 57mm
	21 = 60mm
	22 = 64mm

Prescription Use _____ AND/OR Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S

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