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

April 14, 2015

TheyFit
% Penny Northcutt
Regulatory Consultant
REGSolutions, LLC
174 Watercolor Way, Suite 103-403
Santa Rosa Beach, FL 32459

Re: K150072
Trade/Device Name: TheyFit Male Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: January 12, 2015
Received: January 14, 2015

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 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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150072

Device Name

TheyFit Male Condom

Indications for Use *(Describe)*

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			
E55	B55	S55	
E66	B66	S66	M66
E77	B77	S77	M77
E88	B88	S88	M88
E99	B99	S99	M99
E11	B11	S11	M11
E17	B17	S17	M17
E21	B21	S21	M21
	B22	S22	M22

Legend

Condom Length	**Condom Lay Flat Width**
E = 123mm	55 = 45mm
B = 133mm	66 = 47mm
S = 143mm	77 = 49mm
M = 153mm	88 = 51mm
	99 = 53mm
	11 = 55mm
	17 = 57mm
	21 = 60mm
	22 = 64mm

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

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:	March 19, 2015
APPLICANT:	TheyFit Michael Cecil, MD 4140 Tate Street Covington, GA 30014 Tel: 678-964-2072 Email: mpcecil@earthlink.net
OFFICIAL CORRESPONDENT:	Penny Northcutt, FRAPS, RAC, CQA Regulatory Consultant for TheyFit REGSolutions, LLC Tel: 678-428-6978 Fax: 866-630-4082 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:	TheyFit Male Condom, K122219

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 34 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.

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The sizes available are as follows:

TheyFit Male Condom Model Number Chart			
E55	B55	S55	
E66	B66	S66	M66
E77	B77	S77	M77
E88	B88	S88	M88
E99	B99	S99	M99
E11	B11	S11	M11
E17	B17	S17	M17
E21	B21	S21	M21
	B22	S22	M22

Legend

Condom Length	Condom Lay Flat Width
E = 123mm	55 = 45mm
B = 133mm	66 = 47mm
S = 143mm	77 = 49mm
M = 153mm	88 = 51mm
	99 = 53mm
	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 device have different technological characteristics. The different technological characteristics of the subject device include its available size range compared to the predicate device. These different characteristics of the subject device could affect safety and effectiveness, (e.g., clinical slippage and breakage rates).

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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 D3492-14 and ISO 4074:2014 Acceptance criteria met
Water Leak	ASTM D3492-14 and ISO 4074:2014 Acceptance criteria met
Dimensional Analysis	ASTM D3492-14 and ISO 4074:2014 Acceptance criteria met
Clinical Performance	A customer survey clinical study was conducted to confirm performance of the TheyFit Male Condom in smaller sizes. <u>Study Design</u> A prospective study by surveying customers who used a minimum total of 200 condom uses was conducted to assess the clinical performance of TheyFit condoms in length dimensions less than 160mm and greater than 120mm (TheyFit sizes M, S, B, E). The pre-specified end point was a total clinical failure rate < 5%. <u>Methods</u> Participants for the study were recruited from TheyFit customers who had ordered a condom in the eligible size range and agreed to be contacted regarding the study. For individual condom use episodes to be eligible for inclusion into the study dataset, participants had to report using the condom only for vaginal sex at each condom use event. <u>Results</u> The final sample included a total of 203 condom use surveys. There were three clinical breakages, three clinical slippages during vaginal intercourse, and three slippages during withdrawal. Based on the information provided in the survey responses, it is unknown whether the three slippages during withdrawal occurred as a result of user error. ISO/DIS 29943-1:2014, Condoms -- Guidance on clinical studies -- Part 1: Male condoms, clinical function studies based on self-reports defines clinical slippage as when the condom “slips completely off during intercourse or

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Description	Summary and Conclusion
	during withdrawal from the vagina." However, ISO/DIS 29943-1:2014 also states the "slippage occurring because the user failed to hold onto the condom at the base of the penis during withdrawal and/or because delayed withdrawal are considered user failures and should be recorded as non-clinical slippage." Based on the results of this study, the clinical breakage rate of the TheyFit Male Condoms (sizes E55-M22) is 1.5% (3/203). If the three slippages that occurred during withdrawal are counted as clinical slippages, then the clinical slippage rate is 3.0% (6/203), and the total clinical failure rate is 4.4% (9/203). If the three slippages that occurred during withdrawal are not counted as clinical slippages, then the clinical slippage rate is 1.5% (3/203), and the total clinical failure rate is 3.0% (6/203). In either case, the TheyFit Male Condoms (sizes E55-M22) met the pre-defined total clinical failure endpoint of <5%.

CONCLUSION:
The TheyFit Male Condoms (sizes E55-M22) are substantially equivalent to the proposed predicate device or K122219.