



Food and Drug Administration
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August 14, 2015

Hankook Latex Gongup Co., Ltd.
Yang Ho Dong
CEO
Onbix Corporation
#821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, Seoul, 135-768, KR

Re: K150857
Trade/Device Name: Banana Gold
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
Dated: May 13, 2015
Received: May 20, 2015

Dear Mr. Ho Dong,

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 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)
K150857

Device Name
Banana Gold

Indications for Use (Describe)

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

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.

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510(k) SUMMARY

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

Submitter Information: HANKOOK LATEX GONGUP CO., LTD.
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Date Summary Prepared: Mar 12, 2015

Device Information:
Trade Name(s): **Banana Gold**
Classification Name: condom
Panel: Obstetrics/Gynecology
Product code: HIS

Predicate Device Information:
K896987 / RUBBER CONDOM (NON-COLORED)

Device Description:
Personal hygienic medical devices for contraception and preventing from sexually transmitted disease.

Intended Use:
The Banana Gold condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

- * indications for use
- * technological characteristics
- * performance properties

Summary of the technological characteristics compared to the predicate device
new device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table provided below

Comparison table is as follows

| | New device Banana Gold | Predicate device Rubber Condom - non-colored |
|----------------------------|--|---|
| Manufacturer | Hankook Latex Gongup Co.,Ltd. | same |
| 510(k) Number | K150857 | K896987 |
| Product code | HIS | HIS |
| Indications for use | Latex condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections | same |
| Material | Natural Rubber Latex Drc 60% (high ammonia) | same |
| Biocompatibility | Meets the applicable requirement of ISO 10993 (biocompatibility was conducted on subject device which included color additive) | Meets the applicable requirement of ISO 10993 |
| Shape | Have projected nipple for reservoir (2) Inside equally even (3) Natural latex condom of circular cone type with rim | same |
| Type | Ordinary Type | same |
| Length | 180 min | 180 ± 10 mm |
| Thickness | : 0.07 ± 0.02 mm | same |
| Lubricant | Linear Iydimethylsiloxanepolymer | same |
| Color | GOLD | Non-colored |
| Scent | none | none |

| | | |
|--------------------------|---|------|
| Latex formulation | Natural rubber latex, sulphur, zinc oxide, antioxidant, ammonia water, tamol, silicone oil, corn starch | same |
| Dusting agent | crosslinked corn-starch | same |

Non-Clinical Study performance

To be in compliance with biocompatibility, biocompatibility study has been applied to the new device in accordance with the following standard

ISO 10993 Biological evaluation of medical devices
(biocompatibility was conducted on subject device which included color additive)

ISO 4074:2014 airburst and dimensional specification testing

Conclusion

Based on the information provided in this summary we conclude that **Banana Gold** is safe and effective and substantially equivalent to the predicate device K896987.