LUBRICATED BAGGY CONDOM
SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of the SMDA of 1990.

(A) Substantial Equivalence:

1. Submitted by: Sensicon Corporation
   Address: 2595 Commerce Way
   Vista, CA 92083
   Telephone: (760) 734-6690
   Contact: Jeff D. Grant

2. Natural Rubber Latex products present a risk of anaphylaxis for individuals with Type I immediate hypersensitivity to Natural Rubber Latex (NRL) and can cause less dangerous, but uncomfortable, symptoms in individuals with Type IV delayed hypersensitivity. The synthetic TACTYLON® condom contains neither NRL protein allergens nor sensitizing chemicals. It therefore represents a suitable alternative for latex sensitive individuals. Furthermore, muscle exposure to NRL appears to be one of the primary routes of sensitization for Type I allergies.[1]

3. The TACTYLON® condom is made from styrene-ethylene-butylene-styrene thermoplastic elastomer block copolymer but has physical properties (e.g., strength, elasticity, and tactility) and general form that are substantially equivalent to a NRL condom.

(B) The safety and efficacy of TACTYLON® involves two major issues: the potential allergenicity and toxicity of the material and the efficacy of the material's barrier.

1. The TACTYLON® block copolymer is a compound that meets the FDA requirements for Class VI materials, the most stringent category for nontoxicity. The plasticizer used is a USP recognized by the FDA as safe for human consumption. Toxicity is therefore not a relevant safety issue as evidenced by the following studies of the non-lubricated Standard condom (K911431). Neither primary skin irritation nor vaginal mucosal irritation was found in a rabbit model. There was no evidence of irritation or toxicity in a 3-day, 7-day, or 90-day surgical mucosal implantation study in a rabbit model. Furthermore, no delayed dermal sensitization occurred in a guinea pig model. No mutagenic changes were found in histidine dependent mutant strains of *Salmonella typhimurium* when exposed to

[1] American Academy of Allergy & Immunology: Task force on allergic reactions to latex (committee report). J. Allergy Clin Immunol 1993; 92:16-18.

either saline or DMSO extracts of TACTYLON®. In addition, there were no positive indicators resulting from a Cytotoxicity test, by the USP elution method (MG 057), on samples which had been real-time aged for 14 months. Also, the lubricated condom (K953583) was tested for Cytotoxicity on unaged, as well as aged (oven conditioned), sample at 70°C for seven (7) days with no positive indicators. The lubricated condom was tested for systemic toxicity using Saline and Cottonseed Oil as well as for vaginal irritation in rabbits using saline extract. These tests both meet the USP requirements.

The barrier properties of TACTYLON® are substantially equivalent to NRL as demonstrated by an in vitro challenge with a viral surrogate (ϕ X174) to simulate the HIV (AIDS) measured by an extremely sensitive assay. As with NRL products, however, petroleum-based lubricants should be avoided. Because the chemical structure of the copolymer has no unsaturated bond, TACTYLON® is resistant to conditions such as ultraviolet radiation, ozone, oxygen, heat and humidity, that can accelerate aging and adversely affect barrier properties.

2. Clinical trials conducted on the non-lubricated TACTYLON® material indicated it is nontoxic, nonirritating, and nonsensitizing. In the modified Draize test conducted in 200 human subjects, TACTYLON® was nonirritating and nonsensitizing in all 200 subjects. When a group of 20 latex-sensitive individuals was subjected to use tests and skin prick tests, TACTYLON® caused no adverse reactions.[2]

3. In a clinical trial of TACTYLON® lubricated condoms, the clinical breakage and slippage rates as well as the subjective perceptions were studied. These trials showed that the clinical breakage of the Baggy TACTYLON® condoms were similar to the Standard TACTYLON® condom cleared by 510(k) K953583 and the High Elongation condom cleared by 510(k) K971590.[3]

4. The results of both the nonclinical and the clinical studies suggest that TACTYLON® material is nonallergenic, nonirritating, and nontoxic when in contact with either the intact dermis or mucosal tissue for clinically relevant periods. Furthermore, the barrier was as impermeable to a viral surrogate as NRL in nonclinical studies and tolerated the stresses associated with use as well as NRL in a large clinical trial. The copolymer's chemistry confers a distinct advantage over NRL in terms of potential shelf-life.

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[2]Lahti A, Camarasa JG, Ducombs G, et al: Patch tests with TACTYLON™ in patients with contact allergy to rubber. Contact Dermatitis 1992; 27:188.

[3]Contraceptive Research and Development Program Final Report, April 18, 1997. Comparative Evaluation of Three Tactylon® Condoms with a Latex Condom During Vaginal Intercourse: Breakage and Slippage - Table17.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1997

Jeff D. Grant
Vice President
Sensicon Corporation
2595 Commerce Way
Vista, CA 92083

Re: K974121
Tactylon® Condom - Lubricated, high elongation
(i.e., low modulus) (baggy design)
Dated: October 28, 1997
Received: October 31, 1997
Regulatory Class: II
21 CFR 884.5300/Procode: 85 MOL

Dear Mr. Grant:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: K974121

Company Name: Sensicon Corporation

Device Name: Male Condom

Indications For Use:

For Latex Sensitive Condom Users:

This is a TACTYLON® condom. This is not a latex condom.

You may use this TACTYLON ® condom if you or your partner are allergic to latex.

You should know:

- The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done.
- There are laboratory tests on this TACTYLON® material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.

Latex condoms for men, if used correctly with every act of vaginal intercourse are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974121

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)