

NOV 12 2004

Premarket Notification  
Santé Féminine Limited- SensaTouch™  
August 13, 2004

## Section IX

### 510 (k) Summary K042250

This Summary was prepared in accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92

#### 1. General Information

- **Device Name and Classification**

SensaTouch™ - Breast Self-Exam Glove

21 CFR 892.1710 "Mammographic x-ray System (accessory)"

Class II

- **Contact Name and Address**

Charity Martin  
Santé Féminine Limited  
4859 Martin Court – Suite #5  
Smyrna, GA 30082

#### 2. Performance Standard

No mandatory or voluntary standards are applicable.

#### 3. Substantial Equivalence

The SensaTouch™ - Breast Self-Exam Glove is substantially equivalent to the currently marketed OTC devices, Sensor Pad (K973450), My Breast Friend (K023390), and Aware Pad (K991469).

#### 4. Indications for Use

The SensaTouch™ - Breast Self-Exam Glove is indicated as an aid for performing breast self-examinations.

#### 5. Technological Characteristics

The SensaTouch™ - Breast Self-Exam Glove is a very thin double wall polyurethane glove, 8 inches in diameter containing a small quantity of colored lubricating fluid. The very thin nature of the polyester polyurethane allows the glove to conform to the shape of the tissues underlying it. The very low coefficient of friction property of the silicone fluid in combination with the very thin and flexible glove, provides easy sliding between the upper and lower surfaces of the glove. Therefore, when properly used between the fingers and the soft breast tissues of the patient, a reduction of friction is observed.

**Date Prepared** 13 August 2004



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 12 2004

Aluna Management Co., LLC  
% Ms. Charity Martin  
Operations Engineer  
Santé Féminine Limited  
4859 Martin Ct., Suite #5  
SMYRNA GA 30082

Re: K042250  
Trade/Device Name: SensaTouch™  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo  
imaging system  
Regulatory Class: II  
Product Code: 90 IYO  
Dated: August 13, 2004  
Received: August 20, 2004

Dear Ms. Martin:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



# SECTION VII. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042250

Device Name: SensaTouch™

Indications for Use:

SensaTouch™ is indicated as an aid for performing breast self-examinations.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K042250