3/15/99

K983385

EXHIBIT 1 510(K) SUMMARY 23 Sept 1998

Submitter: Hutchison International Inc.
7949 Jefferson Hwy
Baton Rouge, LA 70809
Telph: 504 927 6800 Fax: 504 927 6874

1. **Classification Name:**

Common Name: Tissue Expanders

Proprietary Name: **HUTCHISON** Inflatable Silicone Tissue Expanders

2. **Establishment Registration Number:**

HUTCHISON INTERNATIONAL registration: 2320466

3. **Device Classification:** Tissue Expanders are unclassified.

4. **Performance Standards:** No performance standards have been established under section 514 of the FD&C Act.

5. **Indications for Use:**

The **HUTCHISON** Inflatable Silicone Tissue Expanders are designed for use in:

- Scar/defect revision
- Reconstruction of the breast following subcutaneous mastectomy and other suitable procedures or trauma
- Breast underdevelopment and combined breast and chest wall abnormalities

6. **Device Description:**

The **HUTCHISON** Inflatable Silicone Tissue Expander is currently manufactured and marketed in Europe. The **HUTCHISON** Inflatable Silicone Tissue Expanders will be sold in the US, sterile for single use only and in double-peel pouches to facilitate aseptic handling during implantation in the patient. Product packaging is designed to allow sterilization gases onto the product and permit proper degassing.

The Silicone Tissue Expanders are constructed from silicone elastomer and consist of a silicone connection tube and an injection site. The injection site is a self-sealing dome valve to allow for sterile saline injections for expanding the implant. The **HUTCHISON** Inflatable Silicone Tissue Expanders will be manufactured and available to physicians with two surface finishes, smooth or textured.

Hutchison Silicone Tissue Expanders are available in various designs and sizes to meet the patient and surgeon's needs. A more detailed description of size and volume is provided in Section 3. The available styles are:

- Round
- Rectangle
- Crescent
- Cylindrical
- Croissant
- U design

The manufacturer, Biosil Ltd., uses a high-strength silicone dispersion to produce the shell. The silicone materials used in producing the shell and the valve assembly have all received full biocompatibility assessment by the raw materials supplier.

7. Biosil has conducted extensive tests of the mechanical properties of the silicone shell and the fused joints, including the results from pre and post sterilization studies of elongation, tensile strength, tear resistance, and valve competence.

Sterility-

Biosil has all implants manufactured in a clean room environment and sterilized by the ethylene oxide method to provide a sterility assurance level (SAL) of 10^{-6}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Hutchison International, Inc.
c/o Eduardo March, RAC
Senior Consultant
AAC Consulting Group, Inc.
7475 Wisconsin Avenue, Suite 850
Bethesda, Maryland 20814

Re: K983385
Trade Name: Hutchison Inflatable Silicone Tissue Expanders
Regulatory Class: Unclassified
Product Code: LCJ
Dated: January 19, 1999
Received: January 20, 1999

Dear Mr. March:

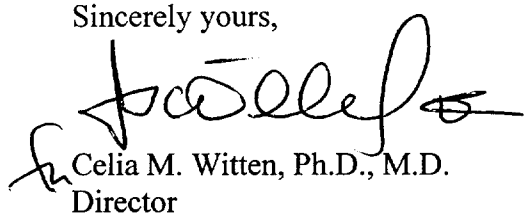
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983385

Device Name: HUTCHISON Inflatable Silicone Tissue Expanders

Indications for Use:

The **HUTCHISON** Inflatable Silicone Tissue Expanders are designed for temporary use in:

- Scar/defect revision
- Reconstruction of the breast following subcutaneous mastectomy and other suitable procedures or trauma
- Breast underdevelopment and combined breast and chest wall abnormalities

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over-the-Counter Use:**
(Per 21 CFR 80.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983385