SEP -1 1999

510(k) Summary
as required by 807.92(c)
for Patton Speculum™
Prepared June 9, 1999

K991963

Submitted by: Patton Medical Corporation
1000 Westbank Drive, Suite 5A200
Austin, Texas 78746
512 329-0469 Fax 512 367-1243

Contact Person: Michael T. Patton
President

Device Trade Name: **Patton Speculum™**

Common Name: vaginal speculum

Classification: nonmetal vaginal speculum

Predicate Devices: **Medscand Disposable Plastic Vaginal Speculum** (K984211), manufactured by Medscand USA, Inc., P.O. Box 7733, Hollywood, FL 33081-1733 and the **Newport Lateral Vaginal Retractor** (K891351), manufactured by Simpson/Bayse, Inc., 430 Ayre Street, Wilmington, DE 19804.

Description of Device:

The **Patton Speculum™** is a handheld mechanical device with a pistol-grip handle, four retracting blades, and a ratchet lock. When the handle is squeezed, the blades move in such a way as to expand the cylindrical surface enclosing them.

Intended Use of Device:

The **Patton Speculum™** is intended for use to retract the vagina in diagnostic and therapeutic obstetrical and gynecological procedures.

Substantial Equivalence to Predicate Device:

The **Patton Speculum™** is substantially equivalent to the combination of two vaginal retractors, or specula. The first is the traditional two-bladed speculum, e.g., **Medscand Disposable Plastic Vaginal Speculum** (K984211), manufactured by Medscand USA, Inc. The second is the lateral vaginal retractor, e.g., the **Newport Lateral Vaginal Retractor** (K891351), manufactured by Simpson/Bayse, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 1999

Mr. Michael T. Patton
President
Patton Medical Corporation
1000 Westbank Drive, Suite 5A200
Austin, TX 78746

Re: K991963
Patton Speculum™
Dated: June 9, 1999
Received: June 10, 1999
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HIB

Dear Mr. Patton:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) NUMBER (IF KNOWN): K991963

DEVICE NAME: Patton Speculum™

INDICATIONS FOR USE:

The **Patton Speculum™** is intended for use to retract the vagina in diagnostic and therapeutic obstetrical and gynecological procedures.

(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 801.109) (Optional Format 1-2

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991963