MAR 2 5 2004

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510(k) SUMMARY (Section E)

1.	Submitted by:	Tools for Surgery, LLC
2.	Address:	1339 Stony Brook Road Stony Brook, NY 11790
3.	Telephone:	(631) 751-6930
4.	Fax:	(631) 751-6932
5.	Contact Person:	Arnold R. Leiboff, M.D.
6.	Date Summary Prepared:	January 6, 2004
7.	Device Trade Name:	Hemorrhage Occluder Pin
8.	Common Name:	Hemorrhage Occluder Pin, also thumbtack
9.	Classification Name:	Staple, Implantable (per 21 CFR, Section 878 4750)

10. Substantial Equivalency is claimed against the following device: Hemorrhage Occluder Pin from Surgin, Inc. 510(k) K890447

11. Description of the Device: The Hemorrhage Occluder Pin is a 7 mm long pin capped with an 8 mm diameter, 1.5 mm thick truncated cone-shaped head. The 1.25 mm diameter pin section has four tissue and bone retaining ridges formed by machining four equally spaced truncated conical sections. It is made of medical grade titanium suitable for implantation.

12. Intended use of the device: This device is indicated to control severe presacral hemorrhage during pelvic surgery.

13. Safety and effectiveness of this device: This device is as safe and effective as the predicate device cited above. See tabulated comparison (paragraph 14 below) to validate this claim.

14. Summary comparing technological characteristics with the predicate device. Please find below a tabulated comparison supporting that this device is substantially equivalent to the predicate medical device in commercial distribution.

SUBSTANTIAL EQUIVALENCE COMPARISON K994149 (p. 2 of 3)

	Proposed Device	Predicate Device
Intended Use	For the control of localized severe hemorrhage from the presacral area during surgery.	Exactly the same
Indications for Use	When other techniques (cautery, suture, clamping, etc.) are judged ineffective.	Exactly the same
Target Population	All males or females with the above indication for use.	Exactly the same
Design	See item 11 of 510(k) summary (page 4.1) and drawing (page 4.4) The proposed device was developed by reverse engineering the predicate device.	Exactly the same
Materials	Machined from medical grade 6AL4V titanium as are many orthopedic devices such as hip and knee joints and pins, plates and screws, etc. used for internal and external bone fracture fixation	Exactly the same
Performance	Sterile single use device is pressed thru the tissue and imbedded in the bone at the presacral hemorrhage site (using fingertip pressure) until the head is seated and the bleeding controlled. The pin, abetted by the ridges on the pin, remains implanted in the bone. Clinical experience of the product device validates the performance.	Exactly the same
Biocompatibility	Titanium is known to be completely inert and immune to corrosion by all body fluids and tissue and is capable of joining with bone and other tissue. Also, the prior clinical experience with the predicate pins of the same material, sterilized and implanted in the sacral area during pelvic surgery validates the biocompatibility .	Exactly the same, ie same manufacturing process, same chemical composition, same body contact and equivalent sterilization method.
Mechanical Safety	Supported by materials high strength, corrosion resistance, ability to withstand repeated sterilizations without compromise to edge or surface quality and by its identical design to the predicate device with its long successful clinical usage	Exactly the same
Chemical Safety	Supported by safe usage of much larger volume of identical material in imbedded prostheses and the materials bio-compatibility.	Exactly the same

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Anatomical Sites	Only site indicated for usage is in the sacral area during pelvic surgery.	Exactly the same
Human Factors	Not an issue. Only finger pressure required to pierce tissue and to press pin into the bone.	Exactly the same
Energy Used or Delivered	None.	None
Compatibility with environmental and other devices	Material is highly inert, chemically safe and non-magnetic and is thus no threat to environment or sensitive implanted devices, electronic or otherwise.	Exactly the same
Standards Met	MIL-T9047 6AL4V EL1 ASTM F136.	Exactly the same
Electrical Safety	Device is passive. No electrical input, output or generated power.	Exactly the same
Thermal Safety	Device is passive, not heat generating, and immune to damage from external heat within range the body can otherwise sustain without fatal consequences.	Exactly the same
Radiation Safety	Device is immune to damage by any level of radiation exposure the body can sustain and does not emit any radiation.	Exactly the same
Sterility	The device is to be marketed both as "unsterilized" and as "sterilized". The latter will be ETO sterilized and validated in accordance with ANSI/AAMI 11135-1994 and EN550. Sterilization validated per method "c", half cycle method. For the sterilized device the packaging shall be a double barrier consisting of a tyvek-styrene tray in a tyvek-polyethylene pouch with a five year expiration. A packaging aging study will be completed by a certified testing facility to validate this claim.	Radiation sterilization when marketed as sterilized. Packaging and expiration is exactly the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2004

Arnold R. Leiboff, M.D.
President
Tools For Surgery, LLC
1339 Stony Brook Road
Stony Brook, New York 11790

Re: K040109
Trade/Device Name: Hemorrhage Occluder Pin
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: January 6, 2004
Received: January 20, 2004

Dear Dr. Leiboff:

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.

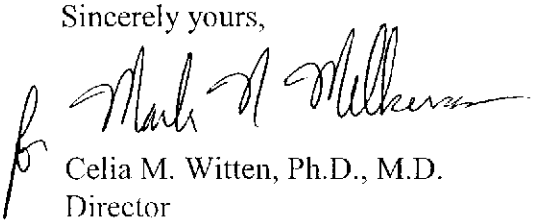
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K040109

Device Name: Hemorrhage Occluder Pin

Indications For Use:

The Hemorrhage Occluder Pin is indicated for the control of localized severe presacral hemorrhage during pelvic surgery, i.e., to occlude internal tissue to stop hemorrhage and aid healing.

Prescription Use __x_____ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040109