

SEP 8 1999

K992640

## 510(K) SUMMARY

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

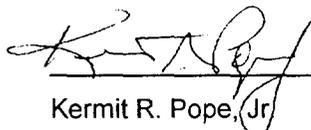
This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR §807.92.

Minumys Surgical intends to introduce into commercial distribution the *Slimline* Surgical Clamp and *Slimline* Jaw Inserts. The equivalent predicate devices are Allegiance Healthcare's Fogarty Surgical Clamp (preamendment) and Baxter International's Safejaw Inserts (see copy of Product Insert Sheet in Attachment 2).

The FDA has classified surgical instruments for clamping as Class I devices (21CFR878-4800). The FDA has also classified vascular clamps as Class II devices (21CFR870-4450). Minumys' *Slimline* Surgical Clamp and *Slimline* Jaw Inserts are a Class II medical device. The common name for Minumys' device is: Surgical Clamp.

Minumys' *Slimline* Surgical Clamp with *Slimline* Jaw Inserts and Allegiance's Fogarty Surgical Clamp with Baxter's Safejaw Inserts are surgical clamps intended for use in vascular or general surgery. The *Slimline* Surgical Clamp and *Slimline* Jaw Inserts are substantially equivalent in terms of intended use, principles of operation, basic technological characteristics, and target population of surgical disciplines.

The *principle of operation* for occlusion with these clamps is the *squeezing together of the jaws* to temporarily occlude vessels. The need for clamping is present in most surgical specialties. The device labeling supports the use of these devices for vascular and general surgical applications in surgery.

 8/2/99  
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Kermit R. Pope, Jr. Date  
President/CEO

Minumys Surgical  
10231 Bubb Road  
Cupertino, CA 95014  
(408) 873-3161



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Noel Messenger  
Regulatory Consultant  
Minumys Surgical, Inc.  
10231 Bubba Road  
Cupertino, California 95014

Re: K992640  
Trade Name: SlimLine Surgical Clamp and SlimLine Jaw Inserts  
Regulatory Class: II  
Product Code: DXC  
Dated: July 28, 1999  
Received: August 6, 1999

Dear Mr. Messenger:

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.

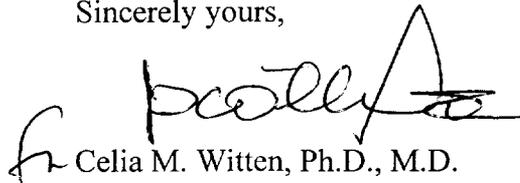
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Noel Messenger

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large, prominent initial "C".

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: K992640

Device Name: SlimLine Surgical Clamp and SlimLine Jaw Inserts

## Indications For Use

### For Vascular Work

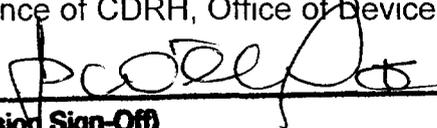
- Suitable for veins and arteries.
- Performs efficiently on either diseased or normal vessels.
- Provides occlusion of atherosclerotic vessels without excessive closing forces.
- Minimizes intimal damage and fragmentation of atherosclerotic material.
- Can be clamped over indwelling catheters.

### For Gastrointestinal Work

- Replaces bulky, rubber shod clamps
- Cushion-design of inserts enables occlusion without crushing the bowel.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices  
510(k) Number \_\_\_\_\_

K992640

Prescription Use

OR

Over-The-Counter Use