DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 1999

Ms. Dagmar S. Maeser
C/O Geister Medizintechnik GMBH
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K982365
Trade Name: Atraumatic Clamps, Bulldog Clamps, Micro Vascular Clamps and Applying Forceps
Regulatory Class: II
Product Code: DXC
Dated: January 27, 1999
Received: January 29, 1999

Dear Ms. Maeser:

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) 594-4586. 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" (21CFR 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4/8/99

K982365

Geister Medizintechnik GmbH

510(k) Number: _____

Device Name: Vascular Clamp

Classification Name: Vascular Clamp

Product Code: 74 DXC Class II 21 CFR 870.4450

INDICATIONS FOR USE:

Atraumatic Clamps and Bulldog Clamps

Intended Use:

To temporarily occlude an artery or vein with correct tension to produce minimal trauma to vessels. The different sizes and models are designed according to the type and size of the blood vessels, anatomical sites, and surgical techniques.
Bulldog clamps are self-closing and are used for small vessels. The closing pressure of the GLOVER clamps can be adjusted using a nut and spring.

Varieties: - Various jaw types (straight, curved, or angled)

Dimensional Ranges:

Lengths:	10.0 – 335 mm
Jaw Widths:	0.8 - 10 mm
Jaw Lengths:	5.0 - 200 mm

(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 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982365

510(k) Number: _____

Device Name: Vascular Clamp

Classification Name: Vascular Clamp

Product Code: 74 DXC Class II 21 CFR 870.4450

INDICATIONS FOR USE (continued):

Applying Forceps

Intended Use:
Applying forceps are used to apply bulldog clamps in deep surgical wounds.

Varieties: Various mouth pieces

Length: 190 – 240 mm

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) **V**

(Optional Format 1-2-96)

for KJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices k982365

510(k) Number: _____

Device Name: Vascular Clamp

Classification Name: Vascular Clamp

Product Code: 74 DXC Class II 21 CFR 870.4450

INDICATIONS FOR USE: (continued):

Micro Vascular Clamps

Intended Use

To secure vascular occlusion of small vessels during surgery and to secure vascular occlusion during pediatric surgery.

Varieties: Single clamps or double clamps
- With or without frame
- With or without approximator (movable)
- Different types for veins or arteries
- Two models (Acland and Acland mod.)
- For various vessel sizes
- Plain or black (Acland mod.)

Dimensional Ranges:

For Vessel Sizes:	0.3 - 5.0 mm
Widths (without frames):	1.0 – 3.0 mm
Lengths:	7.0 – 36.0 mm

(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 1-2-96)

V

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

K982365