

JUN - 8 2000

Attachment 2

510(k) SUMMARY

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

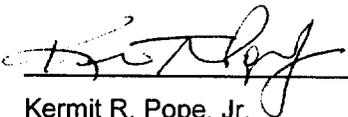
This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR §807.92.

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

The FDA has classified vascular clamps as Class II devices (21CFR870-4450). Novare *ENGAGE* Inserts are a Class II medical device. The common name for Novare's device is: Surgical Clamp / atraumatic insert.

ENGAGE Jaw Inserts are used with a surgical clamp to occlude a blood vessel temporarily and may be used to clamp over indwelling catheters. *ENGAGE* Jaw Inserts are adaptable to Fogarty Hydra-Grip Surgical Clamps. This surgical clamp is intended for use in vascular surgery. The *ENGAGE* Inserts and Safejaw 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 vascular procedures. The device labeling supports the use of these devices for vascular applications in surgery.

 12/17/99

Kermit R. Pope, Jr.

Date

President/CEO

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 8 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Terry Buelna
Vice President, Chief Technical Officer
Novare Surgical Systems
10231 Bubb Road
Cupertino, CA 95014

Re: K992980
Trade Name: Engage Jaw Inserts
Regulatory Class: II (two)
Product Code: DXC
Dated: May 15, 2000
Received: May 17, 2000

Dear Mr. Buelna:

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.

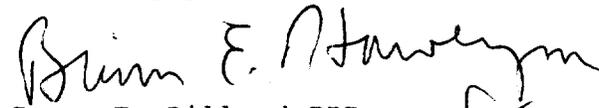
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: *K992980*

Device Name: *ENGAGE* Jaw Inserts

Indications For Use

For Vascular Work

- Suitable for veins and arteries
- *ENGAGE* Jaw Inserts are used with a surgical clamp to occlude a blood vessel temporarily and may be used to clamp over indwelling catheters.
- *ENGAGE* Jaw Inserts are adaptable to Fogarty Hydragrip® Surgical Clamps.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use