510(K) SUMMARY
(as required by 807.92(c))

K970900

MAY 22 1997

Submitter of 510(k):

Contour Fabricators, Inc.
4100 East Baldwin Rd.
Grand Blanc, MI 48439

Phone: (810)695-2910
Fax: (810)695-5336

Contact Person: Michael W. Czop

Date of Summary: March 7, 1997

Trade Name: Instrument Holder

Classification Name: n/a

Predicate Device: Tecnadyne Scientific Incorporated,
"Technadyne Endoscopic Instrument Holder"
K940891

Device Description: The sterile, disposable instrument holder is made of 8 mil vinyl. The overall dimensions of the device are 7.25" x 8.5". The vinyl is heat sealed to create 6 pockets to allow for easy instrument storage and retrieval. Pocket sizes are as follows:

(1) pocket at 4"x3.75"
(1) pocket at 4"x6"
(2) pockets at 2"x3.75"
(2) pockets at 2"x6"

Intended Use: The disposable, sterile instrument holder is intended to be an easily positioned sterile support for surgical instruments. Pressure sensitive adhesive strips are included to allow easy application of the holder to a dry operating room surface.

Examples of possible instruments held by this device are lightweight microsurgical instruments, bipolar forceps, or suction tube tips.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Mr. Michael W. Czop
Contour Fabricators, Inc.
PO Box 56
Grand Blanc, Michigan 48439

Re: K970900
Trade Name: Instrument Holder
Regulatory Class: II
Product Code: GCJ
Dated: March 7, 1997
Received: March 11, 1997

Dear Mr. Czop:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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,

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 (if known): K970900

Device Name: Instrument Holder

Indications for Use:

The disposable, sterile instrument holder is intended to be an easily positioned sterile support for surgical instruments. Pressure sensitive adhesive strips are included to allow easy application of the holder to a dry operating room surface.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970900

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Optional Format 1-2-96