

K970083

P173

807.92 510(k) Summary

JUN 17 1997

Subject Device: DynaBite HOT Gastroenterology Biopsy Forceps

Manufacturer: Portlyn Corporation

Predicate Device 1: MicroVasive Hot Biopsy Forceps

Distributor: Boston Scientific Corporation

Predicate Device 2: Hot Biopsy Forceps

Distributor: Olympus

Predicate Device 3: DynaBite GI Biopsy Forceps (non-electric)

Manufacturer: Portlyn Corporation

Subject Device Description: The DynaBite HOT Gastroenterology

Biopsy Forceps are manually operated, hand held, flexible, cable

actuated, coated, monopolar, trans-rectal surgical instruments

have diameters of either 2.2, or 3.3 millimeter and working

lengths of 240 centimeter. Each forceps has a pair of double

actuating, fenestrated cup jaws at the distal end. Both devices

are used in endoscopic procedure for removing histological tissue

samples from the inner walls of the intestines and for performing

associated electrocautery. The subject device is intended to be

K970083
P293

used with a colonoscope, a connecting cable and a high-frequency electrical-current generator, manufactured by others. The distal jaws of the forceps are open and closed with a two bar linkage actuated by lateral motion of the proximal finger rings. Since the forceps are fabricated from electrically conductive stainless steels, the forceps may be used to transmit a high frequency wave form to the distal end of the forceps for electrocautery. A dielectric forceps coating and the endoscope electrically insulate the length of the forceps from unintended patient contact. The technological characteristics of the DynaBite HOT Gastroenterology Biopsy Forceps are time tested and used by other legally marketed HOT biopsy forceps.

Intended Use: The DynaBite HOT Gastroenterology Biopsy Forceps used in endoscopic procedure for removing histological tissue samples from the inner walls of the intestines and for performing associated electrocautery. The subject device is intended to be used with a colonoscope, a connecting cable and a high-frequency electrical-current generator, manufactured by others. The

K970083
P3073

intended use and technological characteristics of the subject device is the same as the first two predicate devices. The third predicate device differs only in the electrocautery feature.

I, to the best of my knowledge, believe that all data and information submitted in this 510(k) premarket notification is truthful and accurate and that no material facts have been omitted.


George A. Lyna

1/8/97
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1997

Mr. George A. Lyna
Manager Quality and Regulatory Affairs
PORTLYN CORPORATION
Medical Products Division
RFD 1, Box 451, Route 25
Moultonboro, New Hampshire 03254

Re: K970083
DynaBite Hot GI Biopsy Forceps
Dated: May 19, 1997
Received: May 20, 1997
Regulatory class: II
21 CFR §876.4300/Product code: 78 KGE

Dear Mr. Lyna:

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 (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 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) 594-4616. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

Page 1 of 1

510(k) Number (if known): K970083

Device Name: DynaBite HOT GI Biopsy Forceps

Indications For Use:

The DynaBite HOT Biopsy Forceps is intended for uses in a gastrointestinal endoscopic procedure for removing histological tissue samples from the inner walls of the intestines and for performing associated electrocautery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Robert R. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970083