



916-342-4133
FAX: 916-343-4541

K970819

JUL 14 1997

05 February 1997

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Unknown
Common/usual name: Laser needle positioner, stereotactic needle guide, needle guide, etc.
Proprietary name: TargoBeam

- B. Substantial equivalence: Hawkins Blunt Needle Access System (Medical Device Technologies), SiteRite II Vascular Access Guidance System (Dymax Corporation), ColorMark (EchoCath, Inc.), AccuPlace (Medtronic Interventional Radiology).

- C. Device description: The TargoBeam is an aiming device which utilizes lasers to precisely place the correct angulation and position on an interventional device such as a biopsy needle.

- D. Intended use: The TargoBeam is intended to be used to verify and control correct angulation of interventional devices such as needles used in CT- or MRI-guided punctures, biopsies, and

related procedures.

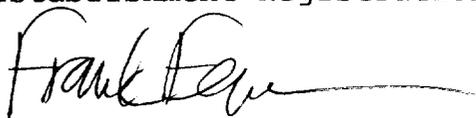
E. Technological characteristics: The TargoBeam device is similar to predicate devices, and existent methodologies in its intended use.

The proposed device is different than many needles in that the TargoBeam is entirely non-invasive, and suitable for use under MRI.

Submitted,

FERGUSON MEDICAL

Establishment Registration Number 2937794

A handwritten signature in cursive script, appearing to read "Frank Ferguson", with a long horizontal flourish extending to the right.

Frank Ferguson
Official Correspondent



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Frank Ferguson
Official Correspondent
Ferguson Medical
3407 Bay Avenue
Chico, California 95926

Re: K970819
TargoBeam (Laser Needle Positioner)
Dated: June 20, 1997
Received: June 27, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

JUL 14 1997

Dear Mr. Ferguson:

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.

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) 594-4613. 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

510(k) Number (If known): K970819

Device Name: TargoBeam

Indications For Use:

TargoBeam is an aiming device intended to be used to verify and control correct angulation of interventional devices such as needles used in CT- or MRI-guided punctures, biopsies, and related procedures.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K970819

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)