



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2001

Mr. William J. Griffin
QS&RA Manager
Hayes Medical, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762-9623

Re: K003649
Trade Name: Triton Hip System
Regulatory Class: II
Product Code: LWJ, JDI, MEH and LZO
Regulation: 21 CFR 888.3350
Dated: November 20, 2000
Received: November 27, 2000

Dear Mr. Griffin:

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.

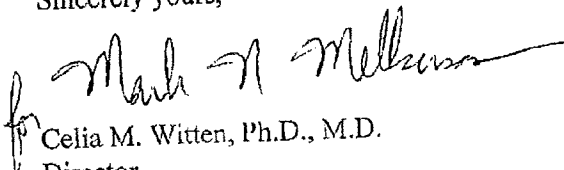
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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) 594-4659. 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,


for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Hayes Medical, Inc.

ID:916-355-7190

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K003649

Section 8 Statement of Indications for Use

Indications for use of the TRITON HIP SYSTEM:

- A) Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B) Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
- C) Proximal femoral fractures.
- D) Avascular necrosis of the femoral head.
- E) Non-union of proximal femoral neck fractures.
- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.
- G) Indications for the use of the Triton Hip System must be carefully considered with respect to the patient's entire evaluation and alternative procedures. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding activity and joint loading are assured. This includes all patients who may or may not have multiple joint involvement, for whom restoration of joint mobility leads to an expectation of greater mobility and an improvement in the quality of life.

for Mark N. Melanson

 (Division Sign-Off)
 Division of General, Restorative
 and Neurological Devices

510(k) Number _____ *K 003649*