JUL 17 2002

Summary of Safety and Effectiveness information Premarket Notification, Section 510(k)	***HLS NOETOS System*** Tornier S.A.

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

K013906
page 1 of 3

1) Device name

Trade name: ***HLS NOETOS System***
Common name: Total anatomical knee prosthesis
Classification name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained

2) Submitter

Tornier S.A.
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3) Company contact

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4) Classification

Sec. 888.**3560** Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
(a) Identification. A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (Sec. 888.3027).
(b) Classification. Class II.

Device class: Class II
Classification panel: Orthopedic
Product code: 87JWH

5) Equivalent / Predicate device

ROTAGLIDE + Total Knee System, Corin Medical (K000232),
INSALL/BURSTEIN II, Zimmer (K872379),
PFC Modular Total Knee System, DePuy (K984158),
NEX-GEN Complete Knee Solution Legacy Posterior Stabilized, Zimmer (K991581).

K013906
page 2 of 3

6) Device description

The usual goal of total knee replacement is to restore the knee joint to its best working condition and to reduce or eliminate pain. The *HLS NOETOS System* is intended to accomplish these goals. The *HLS NOETOS System* is intended for use as a total knee replacement system sacrificing the cruciate ligaments. The *HLS NOETOS System* provides the flexibility needed to adapt the implant and the therapeutic solution to the patients need. All the type of implants have been designed with the same objectives:

- to restore the joint line both in flexion and in extension without altering the patellar height,
- to restore the articular morphology and to preserve bone stock.

The design of the implant, particularly the tibial one, guarantees the antero-posterior stability, by a third femoral condyle that engages a tibial cam during flexion.

The *HLS NOETOS System* consists of the association of three components: a femoral component, a tibial tray associated with a polyethylene bearing and a polyethylene patellar implant. The patella can be preserved if it is in good state or resurfaced by the patellar implant.

7) Materials

The femoral part is manufactured from Cobalt-Chromium alloy according to ISO standard 5832-4. The articulating surface, in contact with the bearing component, is mirror polished and the finished aspect of the part in contact with the bone is fine shot-blasted. The tibial tray is also made from Cobalt-Chromium alloy according to ISO standard 5832-4. The finished aspect is fine shot-blasted. The extension tibial stem and the tibial plug are also made from Cobalt-Chromium alloy according to ISO Standard 5832-7 or ISO Standard 5832-12. The fixed bearing component and the patella are manufactured from implant grade ultra-high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.

8) Indications

This device is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis. This device is also indicated for the revision of knee prosthesis.

The HLS NOETOS cemented system with fixed tibial bearing is intended for cemented use only.

K013906
page 3 of 3

9) Comparison table

		HLS NOETOS System	**ROTAGLIDE+ Total Knee System**	**INSALL/ BURSTEIN II posterior-stabilized**	**PFC Modular Total Knee System**	**NEX-GEN Complete Knee Solution LPS**	SE?
Materials	Femoral part	CoCr	CoCr + plasma spray	CoCr	CoCr	CoCr	YES
	Tibial bearing	UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE	YES
	Tibial tray	CoCr	CoCr + plasma spray	Titanium alloy	Titanium alloy	Titanium alloy	YES
	Patella	UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE	YES
Posterior stabilized		yes	yes	yes	yes	yes	YES
Method of Fixation		Cemented	same	same	same	same	YES
Indications for Use		Total knee replacement	same	same	same	same	YES
Standards Specifications CoCr		ISO 5832-4 ISO 5832-7 ISO 5832-12	same	ASTM F 75	ASTM F 75	ASTM F 75	YES
Standards Specifications UHMWPE		ISO5834-2	same	same	same	same	YES
Sterilization method		2.5 Mrad Gamma radiation	same	same	Gamma vacuum foil	same	YES
Manufacturer		TORNIER, SA	Corin Medical	Zimmer	DePuy	Zimmer	-
K-number		K013906	K000232	K872379	K984158	K991581	-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Ms. Mireille Lémery
Regulatory Affairs & Quality Engineer
Tornier S.A.
ZIRST – 161, rue Lavoisier
38330 Montbonnot
France

Re: K013906
Trade/Device Name: HLS NOETOS System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: April 16, 2002
Received: April 18, 2002

Dear Ms. Lémery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Mark N Melkerson

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

510(k) Number (if known): **K013906**

Device name: ***HLS NOETOS System with fixed tibial bearing***

Indication for use:

This device is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis. This device is also indicated for the revision of knee prosthesis.

The HLS NOETOS cemented system with fixed tibial bearing is intended for cemented use only.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhauser

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

510(k) Number K013906

Prescription use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)