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

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

MAY 22 2003

1) Device name

Trade name:	***HLS Uni Evolution prosthesis***
Common name:	Unicompartmental Knee Prosthesis
Classification name:	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/Polymer

2) Submitter

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3) Company contact

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4) Classification

Sec. 888.**3520** Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.
(a) Identification. A knee joint femorotibial metal/polymer non- constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device minimally limits (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene and are intended for use with bone cement (Sec. 888.3027).
(b) Classification. Class II.

Device class:	Class II
Classification panel:	Orthopedic
Product code:	HSX

5) Equivalent / Predicate device

Miller / Gallante Precoat Unicompartmental, Zimmer, Inc; K010685
Advance Unicondylar Knee System, Wright Medical Technology, Inc; K014171
Link Endo-Model Sled Uni-Knee, Link America, Inc; K954186

6) Device description

The usual goal of a unicompartmental knee prosthesis is to restore the knee joint to its best working condition and to reduce or eliminate pain when only one side of the joint is affected. The *HLS Uni Evolution prosthesis* is intended to replace the medial or lateral compartment of the femoro-tibial knee joint. This system is an intermediate solution between osteotomy and total prosthesis.

The *HLS Uni Evolution prosthesis* consists of a metallic distal femoral resurfacing component and a tibial component. Two kinds of tibial component may be associated with the femoral component, one that is all polyethylene and one that is polyethylene metal-backed.

7) Materials

The femoral part is manufactured from cast 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 shotblasted. The all polyethylene tibial component is manufactured from implant grade ultra-high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2. The metal backed tibial component is composed of a polyethylene part, made from implant grade ultra-high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2, inserted in a stainless steel metal back that conforms to ISO standard 5832-1.

8) Indications

The *HLS Uni Evolution prosthesis* is intended for the replacement of the medial or lateral compartment of the femoro-tibial knee joint, when only one side of the knee is affected. This device is indicated in case of primary or secondary femoro-tibial arthritis. The *HLS Uni Evolution prosthesis* is intended for cemented use only.

9) Comparison table

		HLS Uni Evolution prosthesis	**Miller / Gallante Precoat Unicompartmental**	**Advance Unicondylar Knee System**	**Link Endo-Model Sled Uni-Knee**	SE?
Materials	Femoral implant	Cobalt Chromium alloy	Cobalt Chromium alloy	Cobalt Chromium alloy	Cobalt Chromium alloy	YES
	All poly Tibial implant	UHMWPE	no	UHMWPE	UHMWPE	YES
	Metal backed component	UHMWPE + Stainless steel	UHMWPE + Titanium alloy	UHMWPE + Titanium alloy	UHMWPE + Cobalt Chromium alloy	NO
Sizes	Femoral implant	5 sizes in 2 thickness (3 & 5 mm)	7 sizes right and left	4 sizes	4 sizes	YES
	All poly Tibial implant	5 sizes in 3 thickness (9, 11 & 13mm)	-	4 sizes in 4 thickness (7, 8, 9 & 10mm)	3 sizes in 2 thickness (11 & 13mm)	YES
	Metal backed component	5 sizes in 3 thickness (9, 11 & 13mm)	5 sizes with 4 thickness (8, 10, 12 & 14mm) right and left	4 sizes in 3 thickness (10, 11 & 12mm)	3 sizes in 4 thickness (7, 9 11 & 13mm)	YES
Method of Fixation		cemented	cemented	cemented	cemented	YES
Indications for Use		Unicompartmental (medial or lateral) knee replacement	same	same	same	YES
Standards Specifications CrCo		ISO 5832-4	ASTM F 75	ASTM F 75	ISO 5832-4	YES
Standards Specifications UHMWPE		ISO 5834-2	ASTM F 648	ASTM F 648	ISO 5834-2	YES
Sterilization method		Gamma radiation	same	unknown	unknown	YES
Manufacturer		Tornier	Zimmer, Inc	Wright Medical Technology, Inc	Link America	-
K-number		pending	K010685	K014171	K954186	-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

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

Re: K022211
Trade/Device Name: HLS Uni Evolution Prosthesis
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSX
Dated: February 20, 2003
Received: February 24, 2003

Dear Ms. Lemery:

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), 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) you may obtain. 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. Milleron

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): K022211

Device name: ***HLS Uni Evolution***

Indication for use:

The *HLS Uni Evolution prosthesis* is intended for the replacement of the medial or lateral compartment of the femoro-tibial knee joint, when only one side of the knee is affected. This device is indicated in case of primary or secondary femoro-tibial arthritis.

The *HLS Uni Evolution prosthesis* 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 Milhan

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

510(k) Number K022211

Prescription use Yes OR Over-The-Counter Use No

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