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AUG 27 2004

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

SURFIX TECHNOLOGIES SA
Parc Tertiaire des Grésillières
7 avenue Jules Verne
44 230 SAINT SEBASTIEN SUR LOIRE - FRANCE

Tel.: (33) 2 40 80 72 38
Fax: (33) 2 40 80 72 39

B. ESTABLISHMENT REGISTRATION NUMBER

Pending

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854

Tel.: (301) 279 -2899
Fax: (301) 294-0126
estrin@yourFDAconsultant.com

DATE OF PREPARATION OF THIS SUMMARY: March 24, 2004

D. PROPRIETARY (TRADE) NAME

SURFIX® Knee Osteotomy System

E. COMMON NAME

SURFIX® pre moulded plate for opening wedge high tibial osteotomy right and left sides
SURFIX® pre moulded plate for closing wedge high tibial osteotomy right and left sides
SURFIX® reinforced and pre moulded plate for closing wedge high tibial osteotomy right and left sides
SURFIX® distal femoral varus osteotomy plate

F. DEVICE CLASSIFICATION NAME

PLATE, FIXATION, BONE (21 CFR PAR. 888.3030)

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G. PROPOSED REGULATORY CLASS

Class II

H. DEVICE PRODUCT CODE

87 HRS

I. PANEL CODE

87 OR Orthopedic

J. DEVICE DESCRIPTION

The SURFIX® Knee Osteotomy System consists of seven different Stainless Steel plates with a locking system between the threaded sockets of the plates and the lock screws. There are six plates for the proximal tibia and one plate for the distal femur. Their fixation is provided by Titanium alloy or Stainless Steel SURFIX® screws and lock screws available in two versions: cancellous bone screws diameter 6.5 mm and cortical bone screws diameter 4.5 mm. The SURFIX® system fixation creates a single implant/screw unit fixed into the bone thanks the lock screw.

INTENDED USE:

The **SURFIX® Knee Osteotomy System** is intended for open and closed wedge osteotomies of the proximal tibia and the distal femur, treatment of bone and joint deformities, and malalignment caused by injury or disease such as osteoarthitis.

INDICATIONS FOR USE:

The **SURFIX® Knee Osteotomy System** is indicated for knee osteotomies including high tibial osteotomy and femoral osteotomy in the cases of osteoarthritis of the medial tibiofemoral compartment with genu varum and lateral gonarthrosis on genu valgum. Examples include:

- Fixation of opening wedge high tibial osteotomy,
- Fixation of fracture of the medial tibial plateau,
- Osteoarthritis of the medial tibiofemoral compartment with genu varum,
- Fixation of closing wedge high tibial osteotomy,
- Fixation of fracture of the lateral tibial plateau,
- Distal femoral varus osteotomy,
- Lateral gonarthrosis on genu valgum.

PREDICATE DEVICE:

The **SURFIX® Knee Osteotomy System** is substantially equivalent to the **Synthes TomoFix™ Osteotomy System** (K023941) and the **Arthrex Modified Osteotomy System** (K014155).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The three systems are recommended for fixation of osteotomies, including high tibial osteotomy and femoral osteotomy.

For the **Arthrex Modified Osteotomy System,** plates and screws are made of Stainless Steel.
For the **Synthes TomoFix™ Osteotomy System**, plates and screws are made of Titanium alloy.
The **SURFIX® Knee Osteotomy System** provides plates made of Stainless Steel and, screws and lock screws made of Titanium alloy or Stainless Steel.

The three systems are fixed with screws.

SUMMARY OF STUDIES:

Dynamic tests determining fatigue strength indicate the good mechanical resistance of the **SURFIX® Knee Osteotomy System**.

Static tests determining bending strength in flexion and twisting of bone plates indicate the similar mechanical behavior of the **SURFIX® Osteosynthesis System** with a common plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

SURFIX Technologies S.A.
C/o Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K041601
Trade/Device Name: SURFIX® Knee Osteotomy System
Regulation Numbers: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: March 24, 2004
Received: June 14, 2004

Dear Dr. Estrin:

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.

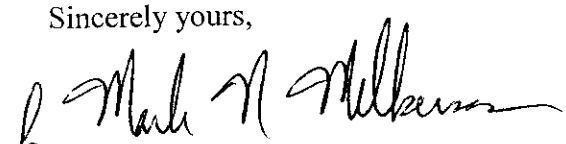
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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) 594-4659. 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 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,



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) : K041601

Device Name : SURFIX Knee Osteotomy System

Indications for Use :

The **SURFIX® Knee Osteotomy System** is indicated for knee osteotomies including high tibial osteotomy and femoral osteotomy in the cases of osteoarthritis of the medial tibiofemoral compartment with genu varum and lateral gonarthrosis on genu valgum. Examples Include:

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- Fixation of fracture of the medial tibial plateau,
- Osteoarthritis of the medial tibiofemoral compartment with genu varum,
- Fixation of closing wedge high tibial osteotomy,
- Fixation of fracture of the lateral tibial plateau,
- Distal femoral varus osteotomy,
- Lateral gonarthrosis on genu valgum.

Prescription Use X OR Over –the-counter Use

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K041601