K013672

510 (k) Summary
[as required by 21 CFR 807.92]

Date Prepared [21 CFR 807.92(a)(1)]
November 1, 2001

Submitter's Information [21 CFR 807.92(a)(1)]

Surgi-Tec S.A.
C/o Joseph Azary
Azary Technologies LLC
P.O. Box 2156
Huntington, CT. 06484

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- Bruges Distraction - Anchoring - Osteosynthesis System

Predicate Device [21 CFR 807.92(a)(3)]

The subject device is substantially equivalent to the following devices:

Subject Device Name	**510k**
Howmedica Leibinger Guerrero-Bell Distractor (or Dynaform)	K972166
Martin Zurich Distraction System	K010139
Medartis MODUS Mandibular Reconstruction System	K992682

Description of the Device [21 CFR 807.92(a)(4)]

The subject device includes several different designs of implantable distractors intended for bone lengthening or stabilization. The subject device is not supplied sterile. The subject device consists of:

Transpalatal Distractor TPB	**Transmandibular Distractor TMD**	**Mandibular Distraction Dynamic Osteosynthesis MD-DOS**
Module Size #1 (1 – 21mm)	Vertical Footplates with rods	Posterior Fixation Unit (PFU)
Module Size# 2 (16 – 31mm)	Osteosynthesis Screws	Fixation Screws
Module Size# 3 (22 – 49mm)		Distraction Unit (DU)
Module Size# 4 (26 – 59mm)		Anterior Fixation Unit (AFU)
Abutment Plate		Spacer
Osteosynthesis Screws		

The subject device requires patient activation at specified times post-operatively using a provided spanner.

The device is composed of Titanium Alloy Grade 2 and 5 per ASTM F-67 and ASTM F-136 requirements.

Intended Use [21 CFR 807.92(a)(5)]

The subject device is intended to be used as a bone stabilizer and lengthening device for the correction of congenital deficiencies or post-traumatic defects of the oral cavity (mandible, ramus, ridge, and palate).

Technological Characteristics [21 CFR 807.92(a)(6)] and Performance Data [21 CFR 807.92(b)(1)]

The subject device has identical material composition and indications for use as the predicate devices. The subject device is based on a similar technological approach by using intra-oral bone-borne titanium components to stabilize and/or lengthen the oral cavity (mandible, ramus, ridge, and palate). Additionally, this device has been successfully used in Europe for several years.

Conclusion [21 CFR 807.92(b)(3)]

The subject device has identical indications for use and similar technological characteristics as the predicate devices. The subject device is composed of Titanium, which is a material used in the predicate devices, as well as a material that has been used successfully in a variety of dental and medical implants over the last several decades. Lastly, clinical usage has found the subject device to produce satisfactory results and function safely as a medical device.

We conclude that the subject device is as safe and effective as the predicate device and does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2002

Mr. Joseph M. Azary
Azary Technologies LLC
P.O. Box 2156
Huntington, Connecticut 06484

Re: K013672
Trade/Device Name: Surgi-Tec S.A. Bruges Distraction-Anchoring-Osteosynthesis Systems
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: February 25, 2002
Received: May 14, 2002

Dear Mr. Azary:

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) 594-4613. 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" (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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 10(k) Number (if known): K013672

Device Name: Surgi-Tec S.A. Bruges Distraction - Anchoring - Osteosynthesis Systems

Indications For Use: The subject device is intended to be used as a bone stabilizer and lengthening device for the correction of congenital deficiencies or post-traumatic defects of the oral cavity (mandible, ramus, ridge, and palate).

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013672