

OCT 31 1997

200 HOLT STREET
HACKENSACK, N.J. 07601

201-487-1838
800-524-0677

FAX: 201-487-5935

Bioelectron, Inc.

200 HOLT STREET
HACKENSACK, N.J. 07601

510(k) Summary

CurvTek TSR System
(Per 21 CFR 807.92c)

K972860

1) Submitter

Bioelectron, Inc.
200 Holt Street
Hackensack, NJ 07601
USA

Telephone Number: 201-487-1838
Fax Number: 201-487-5935

Contact Person: Richard S. Dugot

Date of Summary Preparation: July 10, 1997

2) Device

Trade Name: CurvTek TSR System
Classification Name: Power Instrument, Surgical, Pneumatic and
Accessories/Attachments
Common Name: Surgical Bone Drill

3) Predicate Devices

The CurvTek TSR System claims substantial equivalence to the following
pneumatic surgical instruments/systems/devices:

Romano Modified Glenoid Arcuate Drill	K 885229
Romano Glenoid Arcuate Bone Drill & Disposable Flexi-Bit Units	K 880074
Hall Series 3 Drill and Micro 100	*
MicroAire Power Master and Series 2000 Pneumatic Power Instrument System	*
3M Maxidriver II	K 932307
Synthes Compact Air Drive II	K 971544

* Do not appear to be in FDA database, could be pre-amendment devices.

510(k) Summary (continued)

4) Device Description

The CurvTek TSR System is a pneumatically powered instrument system consisting of a handpiece, disposable single patient use drill bit cartridges, and 510(k) approved accessories. Accessories include Zimmer® (Hall®) style nitrogen hose and sterilization container system.

5) Intended Use

The CurvTek TSR System is used to drill holes in bones except for cranio and maxifacial bones. The system is intended for surgical use for the purpose of soft tissue attachment or wiring/cabling.

6) Basis for Claims of Substantial Equivalence

Bioelectron claims substantial equivalence of the CurvTek TSR System to other pneumatic surgical instrument systems/devices, specifically:

Romano Modified Glenoid Arcuate Drill	K 885229
Romano Glenoid Arcuate Bone Drill & Disposable Flexi-Bit Units	K 880074
Hall Series 3 Drill and Micro 100	*
MicroAire Power Master and Series 2000 Pneumatic Power Instrument System	*
3M Maxidriver II	K 932307
Synthes Compact Air Drive II	K 971544

* Do not appear to be in FDA database, could be pre-amendment devices.

This claim is based on equivalence to:

Intended Use: The intended use of the CurvTek TSR System (with associated accessories) is equivalent to the above instrument systems/devices, i.e. "to drill holes in bones, except for cranio and maxifacial bones," for soft tissue attachment or wiring/cabling.

Materials: The materials of the CurvTek TSR System (CurvTek handpiece and CurvTek cartridges) are stainless steel, aluminum and medical grade plastic. The materials of the predicate devices are the same materials: aluminum, stainless steel, and medical grade plastic.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 1997

Mr. Richard S. Dugot
Vice President - Research & Development
Bioelectron, Inc.
200 Holt Street
Hackensack, New Jersey 07601

Re: K972860
Trade Name: The CurvTek® TSR System
Regulatory Class: I
Product Code: HSZ
Dated: August 1, 1997
Received: August 4, 1997

Dear Mr. Dugot:

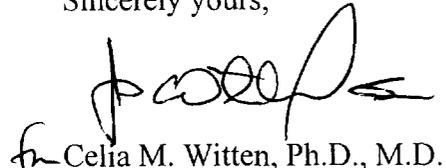
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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) 594-4595. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K972860

Device Name: CurvTek® TSR System

Indications For Use:

The intended use of the CurvTek TSR System is substantially equivalent to the predicate devices listed in this 510(k) application. The device is to be used to drill holes in bone, except for cranio and maxifacial bones, for soft tissue attachment, or wiring/cabling as in the following techniques:

Soft Tissue Repair Techniques

Shoulder

- Bankart Lesion Repair
- Capsular Shift/Capsulorrhaphy
- SLAP Lesion Repair
- Magnuson and Stack Repair
- Rotator Cuff Repair

Knee

- Five-in-One Knee Repair
- Capsule Repair/ Capsulorrhaphy
- Triad Knee Repair
- Quadriceps Femoris Tendon Repair
- Patellar Tendon Repair

Hip

- Reattach Gluteus Medius Take-Down
- Capsule Repair/ Capsulorrhaphy
- Adductor Longus & Gracilis Transfer
- External Oblique Transfer
- Iliopsoas Tendon Transfer

Limb Salvage

- Forearm/Wrist/Hand Reattachment
- Upper Arm Reattachment
- Foot Reattachment
- Lower Leg/Ankle Reattachment
- Thigh Reattachment

Elbow

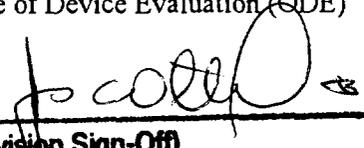
- Fascia Lata Ligament Reconstruction
- Flexorplasty
- Biceps Tenodesis
- Triceps Tendon Repair
- Ulnar or Radial Collateral Ligament Repair

Hand and Wrist

- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Volar Plate Reconstruction
- Triangular Fibro-Cartilage Ligament Repair

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K972860

Prescription Use K
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K972860

Device Name: CurvTek® TSR System

Indications For Use:

The intended use of the CurvTek TSR System is substantially equivalent to the predicate devices listed in this 510(k) application. The device is to be used to drill holes in bone, except for cranio and maxifacial bones, for soft tissue attachment, or wiring/cabbling as in the following techniques:

Soft Tissue Repair Techniques (Con't.)

Foot & Ankle

- Bunionectomy
- Collateral Ligaments Repair
- PT Tendon Advancement
- Achilles Tendon Repair
- Attachment of Distal EHL at Hallux IPJ

Urological

- Retropubic urethral suspension
- Bladder neck suspension

Wiring/Cabbling Techniques

Spine

- Cervical Cabbling
- Lumbar Cabbling
- Osteotomy of Cervical Spine
- Arthrodesis, Lateral Transverse Process

Trauma

- Repair For 3 Part Fracture of Humeral Head
- Treatment of Sternoclavicular Dislocation
- Repair For Olecranon Fractures
- Treatment of Open Patellar Fracture
- Midfoot Reconstruction

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972860

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use