K964252

Section 510(k) Premarket Notification
Summary of Safety and Effectiveness Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

MAY 27 1997

1. **Device Trade Name:** **ORTHO**CHUCK™

2. **Common Name:** Orthopaedic chuck

3. **Classification Name(s):**

   (a) Instrument, Surgical, Orthopaedic, AC-Powered Motor and Accessory-Attachment.

   (b) Instrument, Surgical, Orthopaedic, DC-Powered Motor and Accessory-Attachment.

   (c) Instrument, Surgical, Orthopaedic, Pneumatic Powered Motor and Accessory-Attachment.

4. **Establishment Name & Registration Number:**

   Name: Synergy Medical Products, Inc.

   Number: Pending

5. **Classification:**

   § 878.4820 Surgical instrument motors and accessories or attachments. (a) Identification. Surgical instrument motors and accessories are AC-powered, battery-powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade. (b) Classification. Class I. [55 FR 48440, Nov. 20, 1990]

6. **Device Class:** Class I

7. **Classification Panel:**

   (a) General and Plastic Surgery Devices Panel

   (b) Orthopaedic and Rehabilitation Devices Panel

8. **Product Codes(s):**

   (a) 87KWE (AC Powered)

   (b) 87KIJ (DC Powered)

   (c) 87HSZ (Pneumatic Powered)

9. Contact Person:

Ms. Rhona Porter
Synergy Medical Products, Inc.
3001 Redhill Avenue
Building 2, Suite 103
Costa Mesa, CA 92626
(714) 825-0240 - (714) 825-0204 - FAX

10. Device Description:

The device is a simple barrel shaped plastic outer sleeve that is designed in such a way that when it is in place over a standard ¼" metal head orthopaedic chuck, it allows the surgeon or assistant to quickly and easily insert, drive and or remove any size (up to ¼" dia.) orthopaedic bit or pin.

The device eliminates the necessity to use the usual chuck key such drives ordinarily require. This feature significantly reduces the chance that a glove could be cut or pinched in the exposed metal gears of the chuck and key. Pin holes in surgical gloves have been shown to a potential source of bacterial and/or viral contamination placing patients and health care providers at risk.

Design: The **ORTHO**CHUCK™ is made up of the following 6 components:

1. The Outer Shell or sleeve forms the outer housing of the device. The Outer Shell contains and retains the remaining components and is the user contact part of the device.

2. The Body is that portion of the device that interfaces with the power drive chuck. It also contains and provides the rotational axis for the Face Gear and the Spur Gears.

3. The Face Gear is a cylinder shaped sleeve with a series of circumferential gear teeth. The Face Gear slips over the Body and meshes with and retains the Spur Gears. The outer surface of the Face Gear is provided with a circumferential channel and two locking notches. The channel and locking notches interface with a corresponding pair of linear guides and locking tabs located on the inner surface of the Outer Shell. This feature allows the Face Gear to engage and disengage the chuck teeth by sliding the Outer Shell from a rear (locked) to a forward (unlocked) position on demand.

4. The Spur Gears are slotted tandem gears having both inner and an outer teeth surrounding a central lumen. The gears fit into 3 longitudinal slots in the Body. The Face Gear slides into approximation and locks the Spur Gears into place at the closed end of the 3 longitudinal Body slots.

5. The Rubber Cap is made from an elastomeric material and is press fit into the end of the Body cylinder. The Rubber Cap is centrally fenestrated and is the centering device through which the selected pins, bits, burs and drills are passed into the drive chuck. The central fenestration stretches as necessary to accommodate different shaft diameter implements.

6. The three Locking Pins pass through 3 ports in the Outer Shell, through the central lumen of each of the Spur Gears and insert into the 3 drive chuck key holes. Once inserted and broken off they can't be removed non-destructively. The Locking Pins are the mechanisms that secure and actuate the underlying drive chuck via the Spur Gears, tightening and loosening the chuck jaws as desired. Along with the locking tabs of the Outer Shell, the Locking Pins secure the device directly to the drive chuck until destructively removed at the end of the procedure.

Materials:

1. The Outer Shell or sleeve is made from 6/6 Nylon and 20% Kevlar. The outer shell is either green in color or clear. The clear outer shell is made from medical grade polycarbonate plastic.

2. The Body is made from 6/6 Nylon, 20 % glass, 15% Kevlar and 5% Teflon. The Nylon and additional glass and Kevlar provide additional strength and durability while the Teflon acts as a dry lubricant.

3. The Face Gear is made from 6/6 Nylon, 20 % glass, 15% Kevlar and 5% Teflon. The Nylon and additional glass and Kevlar provide additional strength and durability while the Teflon acts as a dry lubricant.

4. The Spur Gears are made from 6/6 Nylon and 40% Carbon fiber. This particular compound provides additional resistance to wear and has excellent strength characteristics.

5. The Rubber Cap is made from Kraton-G-2705. Kraton-G-2705 thermoplastic rubber compound. The material is designed for use in situations requiring FDA compliance. This material is well suited for use in pharmaceutical closures, syringe bulbs and medical devices.

6. The Locking Pins are made from 6/6 Nylon, 20 % glass, 15% Kevlar and 5% Teflon. The Nylon and additional glass and Kevlar provide additional strength and durability while the Teflon acts as a dry lubricant.

Packaging:

Packaging materials used are industry standard items. The device system utilizes medical grade non-woven peel lid vacuum formed tray-type containers. The device is double packaged to allow for sterile transfer of device to operative field.

Sterilization/Re-sterilization:

The device has been Gamma beam sterilized. The radiation dose utilized exceeds the industry standard 2.5 M/rad dose. The sterilization process has been validated and the sterility assurance level is at least 10^{-6}. The device must be destructively removed from the power drive after use and thus it can't be reused. If a device is opened and not used, it must be disposed of. The materials used in device construction do not allow for gas or steam resterilization.

11. Device Equivalence:

The equivalence of the device is relatively straight forward, in as much as functional and concept characteristics are concerned. The **ORTHO**CHUCK™ is intended to replace the existing small metal "T" handled chuck key with a keyless device. In both instances, a secondary device is manipulated to tighten or loosen the jaws of a Jacob's-type chuck. Thus, functionally, the two devices are essentially identical.

The conceptual issue is also easily evaluated, the concept of a keyless chuck is not new. Several keyless chuck systems have been available for more than 50 years and are evidenced by the Collet-type chuck, the Hudson-type chuck and the generic two-way pin driver. In all these instances, the devices are primary (not adaptable to the Jacob's-type chuck), and are made from various grades of stainless steel and are reusable.

The difference between the **ORTHO**CHUCK™ and other keyless chuck designs is the fact that the **ORTHO**CHUCK™ adapts an existing keyed Jacob's-type chuck to the keyless concept. Additionally, the **ORTHO**CHUCK™ is supplied sterile and is not reusable.

A Comparison table is presented below that graphically demonstrates the important comparison features of selected keyed and keyless devices.

12. Comparison Table

FEATURE	OrthoChuck	Jacob's Chuck W/ Key	Two-Way Pin Driver	SE?
Materials:	Synthetics	Metal	Metal	No
Intended Use(s):	Actuate Chuck of Powered Surgical Drives	Same	Same	Yes
Design:	Cylindrical Sleeve	"T" Shaped Key	Cylindrical Sleeve	Yes
Method of Operation:	Spur Gears Turn Sleeve Gear of Chuck	Same	Same	Yes
Disposable:	Yes	No	No	No
Effect on Chuck Capacity:	None	None	None	Yes
Ease of Use:	On-the-fly One Hand, Insert, Tighten or Loosen	Drive Stopped - Two Hands Required	Drive Stooped - Two Hands Required	No
Effectiveness:	Tightens or Loosens Chuck Jaws	Tightens or Loosens Chuck Jaws	Tightens or Loosens Chuck Jaws	Yes
How Sterilized:	Mfg. Gamma	User - Steam	User - Steam	Yes
510(k) Status:	510(k) Required	510(k) Exempt	510(k) Exempt	NA
K Number	NA	Preamendment	Preamendment	NA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synergy Medical Products, Inc.
c/o Mr. David W. Schlerf
Buckman Company
1000 Burnett Avenue, Suite 450
Concord, California 94520

MAY 27 1997

Re: K964252
Trade Name: OrthoChuck™
Regulatory Class: I
Product Code: GEY
Dated: February 21, 1997
Received: February 26, 1997

Dear Mr. Schlerf:

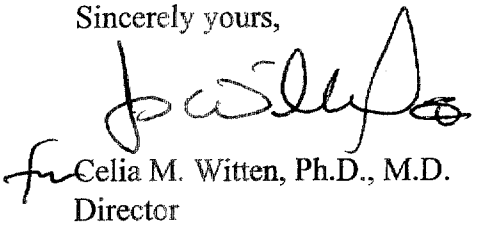
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,



for 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

510(k) Number (if known): K964252

Device Name: OrthoChuck™

Indications For Use:

1. Converts All Standard Keyed Metal Chuck Head Surgical Drives Into Keyless Chuck Drives.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964252

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)