K964444

Appendix B
Summary of Safety and Effectiveness Information

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Safety

Predicate Devices	*QuickLock System*
Radiation Exposure	
Ionizing electromagnetic x-rays are generated by the C-arm image intensifier. Concern for minimizing the risk of x-ray exposure to surgeons and patients is a prominant factor in the free-hand technique currently employed by the predicate devices.	The low-energy, 25 KHz sinusoidal, nonionizing electromagnetic field generated by the probe coils is an nonsignificant radiation hazard* and produces negligible temperature rise of the probe surface. * Opinion of Howard Bassen, Head, Electro-Physics Branch, FDA Office of Science and Technology, telephone conversation July 29, 1994, in which Mr. Bassen confirmed that FDA does not impose standards for electromagnetic radiation unless the device causes heating of body tissue.
Electric Shock	
The C-arm image intensifier is an electronic device. It can contact operating room personnel, surgical apparatus in contact with the patient, or the patient directly, because during the distal targeting procedure it is close to the surgical field and is moved about by a technician to align the x-ray beam with the axis of the target hole. Operating room personnel and patients must, therefore, be protected from electric shock by C-arm compliance with safety standards for electronic medical devices.	The display, probe and guide come into contact with operating room personnel and patients, and are to be certified to UL Standard 544, 2d Edition. The display is in a sturdy, grounded, metal enclosure with 115 VRMS at 60 Hz input power, +/-12 VDC and +5 VDC internal power. Line power is limited by a 250V, 3AG UL 198.6, 2A, FAST type fuse. The AC to DC power supply and electroluminescent display are medical-grade components. Separation and insulation of internal display components prevent shock and fire hazardous conditions. Risk of shock by contact with the probe and guide is eliminated by low voltage levels, isolation, insulation and grounding. The probe coil voltage is below 12 VRMS with polyimide tube insulation breakddown above 1200 V. Probe coils are isolated from the display unit by transformer coupling, and the metal outer surface is grounded through the probe cable shield. Guide components reach voltages far less than 12 VRMS. The guide body is nonconductive, insulated by encapsulation of internal components, and is grounded through a wire in the guide cable.

Predicate Devices	*QuickLock System*
Biocompatibility	
Stainless steel guide wires or rods are routinely placed inside the medullary canal in reduction of fractures, reaming of the medullary canal, and guiding insertion of the nail. They are made of surgical stainless steel, are reusable, and steam or Eto sterilizable.	Probes are placed in nails after surgical insertion into the patient. They are sealed tubes of nickel-titanium alloy (Nitnol SE 508, Nitnol Devices and Componens, Inc.), a material used in the manufacture of vascular stents that are FDA approved for unrestricted implantation. The probe is sealed by laser welding a Nitnol disk into the end inserted into the nail, so there is no patient tissue or fluid contact with probe materials other than Nitnol. Probes are reusable and steam or Eto sterilizable. Probe cables have a silicone jacket and metal connectors that will withstand the same sterilization.
Surgical stainless steel bone drills are supplied with nail manufacturer's instrumentation. They are reusable and steam or Eto sterilizable.	Drills are nonmagnetic, surgical stainless steel (SCF-23, Carpenter Steel Co.). They are reusable and steam or Eto sterilizable.
Drill bushings used in proximal targeting are surgical stainless steel. They are reusable and steam or Eto sterilizable.	Drill bushings are molded USP Class VI biocompatible polysulfone (UDEL P-1700 MG 11, Amoco Performance Products, Inc.). The bushings are reusable and steam or Eto sterilizable.
Drill or trocar holders of radioluscent plastic are used in the Howmedica and Zimmer devices. Radioluscent plastic components are used to hold the bone drill in the Richards and Synthes powered distal tageting devices. These are reusable and steam or Eto sterilizable.	Guides are molded USP Class III biocompatible polyphenylsulfone (Radel R-5000, Amoco Performance Products, Inc.). Guides are reusable and steam or Eto sterilizable. Guide cables have a silicone jacket and metal connectors that will withstand the same sterilization.
Screw drivers are surgical stainless steel, reusable and steam or Eto sterilizable.	Screw drivers are type 316 and 400 series stainless steel. They are reusable and steam or Eto sterilizable.
Safety Standards Certification	
	Certification of compliance with UL Standard 544, 2d Edition will be obtained from an FDA approved testing laboratory before the product is commercially distributed.

Effectiveness

Predicate Devices	*QuickLock System*
Intended Use	
Locate incisions, guide bone drilling, and guide insertion of interlocking screws in the distal targeting procedure of intramedullary nailing.	Same as for predicate devices
Skill and Experience Required	
Users must strive to hold the drill in alignment after short x-ray exposures that provide only intermittent visual control. This requires considerable skill and experience. Surgeons who infrequently perform the procedure fall out of practice and are markedly less effective.	Users have continuous visual control so the task is easier and less training, skill and experience are required. Surgeons learn the technique after a few minutes of training. Proficiency is retained without frequent performance of the procedure.
Accuracy of Visual Cues	
Adjustment of C-arm position to align the x-ray beam with target holes depends on visual perception of distal holes as true circles on the image intensifier screen. Subjective judgement limits reliable accuracy of this alignment. Operator skill strongly affects accuracy of drilling between visual snapshots.	The probe and guide are aligned mechanically with target holes during the calibration process, which electronically offsets errors for each procedure. Drilling accuracy is enhanced by the high visual sensitivity of dot and cross-hair sight adjustments and the continuous display of visual sighting information.
Operator Comfort	
The need to minimize exposure to x-ray radiation hampers the freehand technique used with the predicate devices. Surgeons work in awkward positions, reaching from the side to avoid the x-ray beam.	Because there is no need to stay out of an x-ray beam, surgeons can stand, hold the guide, and drill in a comfortable position.
Quality of Drilled Holes	
Holes started out of alignment must be elongated to pass through the nail and both cortices. This reduces the holding strength and endurance of bone screws and compromises the objective of nail interlocking.	Accurate alignment throughout the drilling process ensures correct hole size and shape, for maximum screw holding strength and endurance.
Nicking of Intramedullary Nails	
Drills often strike the edges of target holes, leaving nicks that can cause stress concentration in the nail material and lead to premature nail breakage due to fatigue fracture.	Improved accuracy reduces the occurance of drill strikes and the resultant risk of induced nail fatigue failure.

Predicate Devices	*QuickLock System*
Time Required for Distal Targeting*	
In 17 procedures (10 femoral and 7 tibial) performed using Richards or Synthes radiolucent drills, the time required for distal targeting averaged 16.1 minutes with a range of 10.4 to 30.0 minutes.	In 22 procedures (13 femoral and 9 tibial) performed using the QuickLock system, the time required for distal targeting averaged 8.1 minutes with a range of 5.2 to 14.0 minutes. These data are scewed by changes in probe configuration during the trials; the average time over procedures performed with the final probe configuration was 6.6 minutes.

* Results of clinical trials performed at the University of Arizon Health Sciences Center, Tucson, Arizona, from September 1995 to present. These trials are conducted under IRB classification as a non-significant risk device, with approval by FDA, Center for Devices and Radiological Health IDE section's Mr. Ted Stevens, team leader of orthopedic devices, non-implantable. The principal investigator was John T. Ruth, M.D., Assistant Professor, Section of Orthopedic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Roy B. Hollstien, Ph.D.
RDH Medical
5775 Webster Road
Paso Robles, California 93446

AUG 11 1997

Re: K964444
Trade Name: QuickLock Orthopaedic Targeting System
Regulatory Class: II
Product Code: HSB
Dated: June 27, 1997
Received: June 30, 1997

Dear Dr. Hollstien:

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 requirement, 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) 594-4659. 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): K964444

Device Name: QuickLock Orthopaedic Targeting System

Indications For Use:

The QuickLock Orthopaedic Targeting System is indicated for use whenever distal interlocking screws are placed in intramedullary nails to which the QuickLock System has been adapted by making available accessory adapter components that enable mechanical attachment of the the QuickLock Probe to the nail system proximal instrumentation and alignment of the QuickLock Guide during calibration.

(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 K964444

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)