Summary of Safety Information *Premarket Notification, Section 510(k)*	NOVARE SURGICAL SYSTEMS, INC. SEPTEMBER 19, 2007

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

K072715

Device Name: RealHand™ High Dexterity (HD) Instruments

Common Name(s): Endoscopic instruments

Classification Name(s): Endoscope and Accessories

OCT 16 2007

Manufacturer: Novare Surgical Systems, Inc.
Reg. Number: 2954739
Address: 10440 Bubb Road, Suite A
Cupertino, CA 95014

Classification(s):

Sec. 876.1500 Endoscope and accessories

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807of this chapter, subject to the limitations in 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996.

Device Class: Class II for the requested indications
Classification Panel: Gastroenterology & Urology
Product Code(s): GCJ

Equivalent Predicate Device:

Novare Surgical Systems, Inc. believes that the modified RealHand™ High Dexterity Instruments are substantially equivalent to the following legally marketed device:

- Endolink "RealHand" Articulating Instruments, K071488 - Novare Surgical Systems, Inc., and Endolink "True Movement" Articulating Instruments, K043541 - Novare Surgical Systems, Inc.

- Pajunk Modular Handled Instruments, K033249

- Endopath Endoscopic Instruments, K984240

Device Description:

A new electroconductive pathway was added. This change consists of two basic modifications to the existing instruments: 1) a post was added to attach a third party generator via an insulated commercially available legally marketed cable. 2) an internal jumper was added to conduct current from the post to the internal shaft of the instrument. The substantial equivalence of the changes are based on a comparison of physical and functional attributes of the device contrasted with the Novare predicate and the indications of the Pajunk instruments.

The place of manufacture has not changed. The physical appearance of the device, though slightly different, does not adversely affect the modified device. Functional expectations, material suitability, surgical technique and indications for use are just the same as the comparison devices placed in product code GCJ by FDA.

RealHand™ High Dexterity Instruments are substantially equivalent to the original instruments with respect to functionality and performance characteristics based the following criteria:

1) RealHand™ High Dexterity Instruments provide hemostatic clamping that allows electrocautery and ligature of tissue. The performance of the systems are essentially identical.

2) The RealHand™ High Dexterity Instruments were carefully evaluated and compared with the original Novare device. Documented testing established that the characteristics are equal to the original.

3) The original device was evaluated for proper function during use. The modified RealHand™ High Dexterity Instruments were evaluated using a valid test methodology, including electrocautery function and the test result was equivalent, and

4) the RealHand™ High Dexterity Instruments worked as intended.

Company Contact:

Mr. David Danitz
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Cupertino, CA 95014
408.873.3161

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2007

Novare Surgical Systems, Inc
% Buckman Company, Inc
Mr. David w. Schlerf
Vice President
1070 Concord Avenue, Suite 230
Concord, California 94520

Re: K072715
Trade/Device Name: RealHand™ High Dexterity (HD) Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 19, 2007
Received: September 25, 2007

Dear Mr. Schlerf:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND/GSDB
D.O.
f/t:RPW:kxl:10-04-07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

510(k) Number: K072715

Device Name(s): RealHand™ High Dexterity (HD) Instruments

Indications for Use Statement(s):

The RealHand™ High Dexterity (HD) instruments are intended for grasping, mobilization, dissection, transection, suturing, and/or electrocautery of tissue under direct and endoscopic visualization.

Prescription Use X OR Over-The-Counter Use _____

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, and Neurological Devices

510(k) Number K072715

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