SEP 2 4 2002

K021152

510(k) Summary

ZEUS® MicroWrist™ Surgical System and Accessories

In accordance with 21 CFR section 807.92 Computer Motion is submitting the following safety and effectiveness summary.

1) Submitter Information

Computer Motion. Inc.
130-B Cremona Drive
Goleta, CA 93117

Contact: David Munjal, Ph.D., R.A.C.
Vice President, CA/RA/QA

2) Name of Device:

Proprietary Name:	ZEUS® MicroWrist™ Surgical System (ZEUS System) and Accessories
Common Names:	ZEUS System, ZEUS MicroWrist, ZEUS MW
Classification Name:	Laparoscope, General & Plastic Surgery
Regulation Number:	876.1500
Product Code:	GCJ
Class:	Class II.

3) Substantial Equivalence:

This submission establishes the substantial equivalence of the ZEUS® MicroWrist™ Surgical System and Accessories to two predicate devices:

1. A standard laparoscope with hand-held minimally invasive surgical instruments
2. The Intuitive Surgical da Vinci™ Endoscopic Instrument Control System and Endoscopic Instruments, cleared to market via K990144.

4) Description of the Device:

The ZEUS® MicroWrist™ Surgical System (ZEUS System) and Accessories, consisting of a surgeon console and three table-mounted arms, serves as a platform for holding, positioning, and manipulating endoscopic instruments in order to perform selected surgical tasks. One arm of the ZEUS System incorporates the AESOP® endoscope positioner, which provides the surgeon with a steady view of the internal operating field. The HERMES™ Control Center, which uses voice-recognition technology to control devices outside the sterile field, is a standard component of the ZEUS® MicroWrist™ Surgical System and Accessories, and has been cleared to operate with many ancillary devices.

The ZEUS® MicroWrist™ Surgical System (ZEUS System) and Accessories is designed and tested to the following standards:

- EN60601--1 International Standard for Medical Electrical Equipment
- EN60601-1-1 General Requirements for Safety –Collateral Standard
- EN 60601-1-2 Emissions and Immunity Test Measurements
- UL 2601-1 Underwriters Laboratory
- EN55011/A1; CISPR 11 Conducted & Radiated Emission
- EN61000-4-2 ESD Immunity 4kV contact 8kV air
- EN61000-4-4 EFT Immunity
- EN61000-4-6. Conducted Immunity Tests
- EN 61000-4-3 RF Immunity
- EN 61000-4-5 Surge Immunity

5) Intended Use

The ZEUS® MicroWrist™ Surgical System (ZEUS System) and Accessories are intended to be used to assist a surgeon during procedures such as Laparoscopic Cholecystectomy and Nissen Fundoplication, to hold and position an endoscope, and to control laparoscopic instruments in performance of the surgical tasks of grasping, sharp cutting, blunt dissection, electro-cautery and suturing with knot placement. The ZEUS System is intended to be used by surgeons who are trained in minimally invasive surgery, have successfully completed a ZEUS System training program, and are certified in accordance with their respective hospital's customary practice for ZEUS System use. The ZEUS® MicroWrist™ Surgical System is intended to be used in an operating room environment in which the ZEUS System, the operating surgeon and patient are in the same room.

6) Technological Characteristics in Comparison to the Predicates

The difference between a standard laparoscope and the ZEUS System and Accessories is that a standard laparoscope and its associated instruments are hand-held devices not software-assisted. The daVinci predicate is software-assisted, but there are technical differences between this predicate and the ZEUS System and Accessories. However, the ZEUS System and Accessories is substantially equivalent to a standard laparoscope with its associated hand-held minimally invasive surgical instruments, and to the Intuitive Surgical daVinci Endoscope Instrument Control System and Endoscopic Instruments.

8) Non-Clinical Tests

A hazard analysis and associated validations were completed in response to the new Indication for Use.

9) Clinical Trials

Two extensive, prospective, randomized, concurrently controlled clinical trials compared the ZEUS® MicroWrist™ Surgical System and Accessories to standard laparoscopic surgery to demonstrate substantial equivalence to the predicate devices cited in terms of safety and effectiveness.

10) Conclusion drawn from the Non-Clinical Tests and the Clinical Trials

Data included in this submission, including the results from clinical studies with over 200 patients, demonstrate the safety and effectiveness of the ZEUS® MicroWrist™ Surgical System and Accessories for surgical procedures, such as Laparoscopic Cholecystectomy and Nissen fundoplication. Training is demonstrated by the consistent ability and time to complete a task and procedure successfully. For highly selected uncomplicated Laparoscopic Cholecystectomy and Laparoscopic Nissen Fundoplication, during clinical trials, surgeons trained in the ZEUS System and minimally invasive surgery experienced a minimum 13-case learning curve to approximate procedure time with control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2002

Dr. David Munjal
Vice President Clinical, Regulatory
and Quality Assurance
Computer Motion, Inc.
130-B Cremona Drive
Santa Barbara, California 93117

Re: K021152
Trade/Device Name: ZEUS MicroWrist™ Surgical System and Accessories
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: July 12, 2002
Received: July 23, 2002

Dear Dr. Munjal:

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.

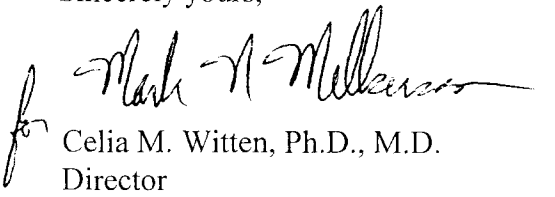
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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" (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,



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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K021152

Device Name: ZEUS® MicroWrist™ Surgical System and Accessories

The ZEUS® MicroWrist™ Surgical System (ZEUS System) and Accessories are intended to be used to assist a surgeon during procedures such as Laparoscopic Cholecystectomy and Nissen Fundoplication, to hold and position an endoscope, and to control laparoscopic instruments in performance of the surgical tasks of grasping, sharp cutting, blunt dissection, electro-cautery and suturing with knot placement. The ZEUS System is intended to be used by surgeons who are trained in minimally invasive surgery, have successfully completed a ZEUS System training program, and are certified in accordance with their respective hospital's customary practice for ZEUS System use. The ZEUS® MicroWrist™ Surgical System is intended to be used in an operating room environment in which the ZEUS System, the operating surgeon and patient are in the same room.

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021152

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)