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Summary of Safety and Effectiveness

K020172
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DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The claim of substantial equivalence is based upon Opus Medical's prior submission for the same device K012125.

COMPANY AND CONTACT PERSON

Opus Medical, Inc.
27127 Calle Arroyo, Suite 1924
San Juan Capistrano, CA 92675
Tel. (949) 234-0400
FAX (949) 234-0493

Contact Person:

Mr. Jim Hart
Tel. 949-234-0400

DEVICE NAME

Opus Magnum® Instrument Set

DESCRIPTION OF DEVICE

The Opus Magnum Instrument Set consists of an Inserter squeeze handle tool with a stainless steel nosepiece.

The Instrument Set is supplied non-sterile.

STATEMENT OF INTENDED USE

The Opus Magnum Anchor and Instrument Set is intended for the fixation of soft tissue to bone for the following indications:

(II) SHOULDER
1.) Rotator Cuff Repair

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICE

The predicate device is used for fixation of soft tissue to bone for shoulder rotator cuff repair.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

The Opus Magnum Instrument Set has the same technological characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2002

Mr. Jim Hart
Opus Medical, Inc.
27127 Calle Arroyo, Suite 1924
San Juan Capistrano, California 92675

Re: K020172
Trade/Device Name: Opus Magnum® Anchor & Instrument Set
Regulatory Class: Unclassified
Product Code: MBI
Dated: April 18, 2002
Received: April 24, 2002

Dear Mr. Hart:

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,

for Mark N Milhern

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

510(k) Number (if known): K020172

Device Name: Opus Magnum® Anchor & Instrument Set

Indications For Use: The Opus Magnum® Anchor and Instrument Set is intended for the fixation of soft tissue to bone for the following indications:

(I) SHOULDER
1.) Rotator Cuff Repair

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** _____
Per 21 CFR 801.109

for Mark N Milleson

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

510(k) Number K020172