510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Act of 1990 and 21 CFR 807.92, OsteoBiologics, Inc. is hereby submitting the 510(K) Summary of Safety and Effectiveness for the ACTAEON™ Probe, 510(k) Number K013429.

Submitter:	OsteoBiologics, Inc. University Business Park 12500 Network, Suite 112 San Antonio, TX 78249-3308 Tel: (210) 690-2131 Fax: (210) 690-2559
Contact Person:	Mark Q. Niederauer, Ph.D., Director of Operations
Date (summary prepared):	October 15, 2001
Trade Name:	ACTAEON™ Probe
Common Name:	Arthroscopic Cartilage Stiffness Tester
Description of Device:	The ACTAEON™ Probe is a hand-held device which when activated by the user measures the reaction force (resistance) of articular cartilage against a known rate and force of indentation applied by the disposable indenting tip of the device.
Indications for Use:	The ACTAEON™ Probe arthroscopic cartilage stiffness tester is indicated for an arthroscopic *in vivo* point measurement of articular cartilage stiffness in humans. The ACTAEON™ Probe can be used arthroscopically or in open joint procedures.
Testing Summary:	The ACTAEON™ Probe is designed to meet and comply with all sections of IEC 60601.
Predicate Device:	Artscan 200 Arthroscopic Cartilage Stiffness Tester Artscan Oy, Helsinki, Finland

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

OsteoBiologics, Inc.
Mark Q. Niederauer, Ph.D.
Director of Operations
University Business Park
12500 Network, Suite 112
San Antonio, Texas 78249-3308

Re: K013429
Trade Name: ACTAEON™ Probe
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: NGR
Dated: October 15, 2001
Received: October 16, 2001

Dear Dr. Niederauer:

We have reviewed your Section 510(k) premarket 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) 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 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

2.4 INDICATIONS FOR USE (FORM)

INDICATIONS FOR USE

510(k) Number (if known): ~~(not known)~~ K013429
Device Name: ACTAEON™ Probe

Indications For Use:

The ACTAEON™ Probe arthroscopic cartilage stiffness tester is indicated for an arthroscopic *in vivo* point measurement of articular cartilage stiffness in humans. The ACTAEON™ Probe can be used arthroscopically or in open joint procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K013429

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