VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Laetitia Bernard
Manager of Regulatory Affairs and Quality Assurance
NuVasive®, Incorporated
10065 Old Grove Road
San Diego, CA 92131
Telephone: (858) 527-1918
Date Prepared: March 14, 2002.

B. Device Name

Trade or Proprietary Name:	*NuVasive® Mesh*
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

C. Predicate Devices

The subject device is substantially equivalent to the Synthes® Synmesh™ System (510([k] submission No. K983766), Depuy-Motech™ Titanium Surgical Mesh (510([k] submission No. K900138), and Sofamor Danek's Timesh™/ Pyramesh™ System (510([k] submission No. K974017/K973145).

D. Device Description

The *NuVasive® Mesh* is a rhombic pattern surgical mesh device intended for the reinforcement of weak bony tissue during orthopedic surgical procedures. The implant is available in preformed round or oval cylinders, in a variety of different sizes.

E. Intended Use

The *NuVasive® Mesh* is indicated for use in the reinforcement of weak bony tissue in orthopedic procedures.

F. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.

Engineering drawings and labeling have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device, including sterilization, and labeling.

G. Summary of Non-Clinical Tests

(Not Applicable).

H. Summary of Clinical Tests

(Not Applicable).

I. Conclusions of Non-Clinical and Clinical Tests

(Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2002

Ms. Laetitia Bernard
Manager of Regulatory Affairs and Quality Assurance
NuVasive®, Incorporated
10065 Old Grove Road
San Diego, CA 92131

Re: K020853
Trade/Device Name: NuVasive® Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: EZX
Dated: March 14, 2002
Received: March 15, 2002

Dear Ms. Bernard:

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" (21 CFR 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 Melkerson

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

1 of 1

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K020853

Device Name: *NuVasive® Mesh*

Indications for Use:

The *NuVasive® Mesh* is indicated for use in the reinforcement of weak bony tissue in orthopedic procedures.

for Mark N Milhouse

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

510(k) Number K020853

Concurrence of CDRH, Office of Device Evaluation (ODE)

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