EXHIBIT 1

TO THE DECLARATION OF BRIAN J. NISBET IN SUPPORT OF DEFENDANTS' OPPOSITION TO NUVASIVE'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND MOTION TO EXCLUDE

NUVASIVE®
Creative Spine Technology®

10065 OLD GROVE ROAD • SAN DIEGO, CA 92131
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www.nuvasive.com

June 25, 2004 Via Federal Express

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Attn.: Division of General and Restorative Devices (HFZ-410)
Re: 510(k) Premarket Notification
NuVasive CoRoent™ System

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act), as amended, and with Title 21 of the Code of Federal Regulations (21 CFR), Part 807, SubPart E, this Premarket Notification is being submitted to advise the Food and Drug Administration (FDA) of the intent of NuVasive to market its vertebral body replacement *CoRoent System*. Pursuant to Title 21 CFR, §807.87, we enclose the following information pertaining to the subject device:

[a] Device Name

Trade or Proprietary Name:	*NuVasive CoRoent™ System*
Common or Usual Name:	Vertebral Body Replacement Device
Classification Name:	Vertebral Body Replacement Device

[b] Manufacturing Establishment Registration Number

NuVasive, Incorporated
10065 Old Grove Road
San Diego, California 92131
Establishment Registration Number: 2031966

Continued . . .

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[c] Classification

Per Title 21 CFR, § 888.3060 a spinal intervertebral body fixation orthosis is identified as:

" ... *a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct "away back" scoliosis (lateral curvature of the spine), or other conditions".*

The NuVasive *CoRoent System* is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The NuVasive *CoRoent System* is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. As such, the subject device is representative of the type of devices described in Title 21 CFR, § 888.3060.

[d] Performance Standards

No performance standards applicable to the subject device have been promulgated as of the date of this submission.

[e] Labeling

Draft labels and labeling for the subject device are described in Section V of the enclosed 510(k) submission, and are contained in an Appendix attached thereto.

[f] Substantial Equivalence

The *NuVasive CoRoent System* has the same intended use, design, materials, performance characteristics, and the same or equivalent labeling, and is therefore substantially equivalent to, other vertebral bode replacement devices cleared by the agency for commercial distribution in the United States. A comparison of all pertinent characteristics of the subject device to its predicate device may be found in Section VI of the enclosed Premarket Notification submission.

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The following information is being submitted in the enclosed Premarket Notification, to establish and support substantial equivalence of the *NuVasive CoRoent System* to medical devices currently cleared by the agency for commercial distribution in the U.S.:

Section I	Premarket Submission Cover Sheet
Section II	Premarket Notification [510(k)] Checklist for Acceptance Decision
Section III	Truthful and Accurate Statement
Section IV	Device Description
Section V	Draft Labeling
Section VI	Rationale for Substantial Equivalence
Section VII	510(k) Summary of Information Supporting Substantial Equivalence
Section VIII	Appendices

For convenience of review, it is suggested that the reader first refer to Section VII for a summary of the information contained in the Premarket Notification, including a description of the subject device, its intended use, and its technological characteristics, as well as identification of commercially available predicate devices, and a summary of the basis for our demonstration of substantial equivalence.

It is the position of NuVasive that the descriptions and information contained in this Premarket Notification constitute confidential commercial information, and we ask that the agency regard the contents of this submission as subject to protection from public disclosure in accordance with the provisions of Title 21 CFR, §21.61.

The intent to market the subject device, and the descriptions and information contained in the enclosed 510(k) Premarket Notification, have not been disclosed to persons outside NuVasive excepting only consultants and/or suppliers subject to non-disclosure agreement. We therefore ask that the agency consider the existence of this submission to be "trade secret" confidential commercial information subject to protection from public disclosure in accordance with the provisions of Title 21 CFR, §807.95(b).

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We understand that the submission to the U.S. Government of false information is prohibited by Title 18 of the United States Code (USC), part 1001, and by Title 21 UCS, Part 331(q).

We trust that the information and descriptions provided in this Premarket Notification will prove sufficient to facilitate a determination of substantial equivalence of the *NuVasive CoRoent System* to other medical devices currently cleared by the agency for commercial distribution in the U.S. If you should have any questions or require additional information, please do not hesitate to contact me at (858) 527-1918, or by telefacsimile at (858) 271-7101.

Sincerely,

Laetitia Cousin
Director of Regulatory Affairs and Quality Assurance

Enclosures: 510(k) Premarket Notification (submitted in triplicate), Sections I through VIII and Appendices, as noted above.

cc: Keith Valentine
Executive Vice President

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