DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1995

Mr. Brian T. Cleary
Director of Regulatory Affairs
Hayes Medical, Inc.
819 Striker Avenue, Suite 10
Sacramento, California 95834-1129

Re: K953198
Corticellous Bone Screw
Regulatory Class: II
Product Code: HWC
Dated: September 18, 1995
Received: September 22, 1995

Dear Mr. Cleary:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on your device being found equivalent only to similar devices labeled and intended for fixation of fractures of the humerus, radius, ulna, femur, tibia, fibula, pelvis and carpal and talar bones. You may, therefore, market your 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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device is intended for the specific intended use(s) described in the first paragraph above only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the labeling must include the following statement, **"WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device for the specific intended use(s) described in the first paragraph above only as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639.

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Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Premarket Notification

510(k) Summary of Safety and Effectiveness Information

DATE OF SUMMARY PREPARATION:

June 7, 1995

MANUFACTURER:

National Medical Specialty, Inc.
Building 203, Avenue B
Youngwood, Pennsylvania 15697-9907
(800) 547-7463

AUTHORIZED REGULATORY AGENT:

Mr. Brian Cleary, Director of Regulatory Affairs
Hayes Medical, Inc.
819 Striker Avenue, Suite 10
Sacramento, CA 95834-5432
(916) 646-5431

DEVICE NAME:

PROPRIETARY NAME: Varifix Bone Screw

COMMON NAME: Orthopaedic Bone Screw

CLASSIFICATION NAME AND REFERENCE: Screw, Fixation, Bone (as per 21 CFR 888.3040)

ESTABLISHMENT REGISTRATION:

The registration number of National Medical Specialty, Inc. is pending.

CLASSIFICATION:

Orthopaedic bone screws are classified under the unique device classification code 87 HWC. See 21 CFR, 888.3040 for additional information regarding this type of medical device. This type of device is presently a Class II medical device. In general, Class II medical devices are subject to "Special Controls."

SPECIAL CONTROLS:

At this time, Food and Drug Administration generated Performance Standards applicable to the Varifix Bone Screw are not in force. National Medical Specialty produces this device using available voluntary standards that are appropriate to the risk that Class II devices reasonably present. Materials and vendor certifications, in-house SOP's and ASTM standards are utilized as appropriate.

INTENDED USE:

The Varifix Bone Screw is a general purpose self-tapping bone screw intended for use in the fixation of bone fractures in a wide range of orthopaedic applications.

DEVICE DESCRIPTION:

The Varifix Bone Screw is a general purpose orthopaedic bone screw which possesses two design features different from comparative standard bone screws. These two distinguishing features of the Varifix design are (1) a tapered minor diameter, and (2) a thread angle which varies along the length of the screw.

Tapered Minor Diameter (Tapered core). *Unlike standard bone screws, which have a constant minor diameter (cyclindrical core),* the minor diameter of the Varifix screw is not restricted to a constant value, but instead increases linearly from the tip of the screw to the head of the screw resulting in a tapered or conically shaped core. The taper is defined by the minor diameter at the tip of the screw, the minor diameter at the head of the screw and the length of the screw. The minor diameter at the tip of the screw is designed such that the device will meet a miminum strength requirement The minor diameter at the head of the screw will be no greater than 80% of the major diameter. The minor diameters for each class are indicated in the table below

Screw Class	Outer Diameter	Thread Crest	Thread Pitch	Lengths	Minimum Minor Core Diameter	Maximum Minor Core Diameter
1. Small Cortical	3.5 mm	0.127 mm	1.25 mm	15 - 110 mm	1.50 - 1.90 mm	2.7 - 2.8 mm
2. Large Cortical	4.5 mm	0.127 mm	1.75 mm	15 - 110 mm	1.50 - 1.90 mm	3.4 - 3.5 mm
3. Small Cancellous	4.0 mm	0.127 mm	1.75 mm	15 - 110 mm	1.50 - 1.90 mm	2.6 mm
4. Large Cancellous	6.5 mm	0.127 mm	2.75 mm	30 - 110 mm	1.50 - 1.90 mm	4.5 mm

Variable Thread Angle. *The design feature unique to the Varifix Bone Screw is the variable thread angle.* The thread angle of the Varifix screw increases in value from the tip of the screw to the head of the screw. The load-bearing face of the buttress thread form is at a constant angle over the entire length of the screw, thus leaving only the orientation of the opposing face of the thread as variable. The angle of the opposing face varies from a minimum of 30° at the tip of the screw to a maximum of 60° at the head of the screw when measured from a line perpendicular to the screw axis. Thus, the thread angle varies from approximately 30° at the tip of the screw to approximately 60° at the head of the screw.

The Varifix Bone Screw will be offered in four classes, each class defined by the major diameter and the thread pitch as indicated in the above table. All threads will be of the buttress form with a near-perpendicular load-resisting flank (face) relative to the screw axis The screw head design is in conformance with ASTM Standard F 543, Standard Specification for Cortical Bone Screws Each class of screw will be offered in a variety of legnths from a minimum length of 15 mm to a maximum length of 110 mm, with intermediate lengths ranging from 20 mm to 100 mm in 10 mm increments.

MATERIALS:

The Varifix Bone Screw is manufactured from 316L Stainless Steel (ASTM F 138).

SUBSTANTIAL EQUIVALENCE INFORMATION:

National Medical Specialty believes that the Varifix Bone Screw is substantially equivalent to many currently marketed bone screw devices. The materials, intended use, indications for use, method of sterilization, cautions and precautions are substantially the same. The design of the Varifix Bone Screw differs only in its tapered core and variable thread angle.

In addressing the design differences between the Varifix Bone Screw and standard bone screws, it need be mentioned that the concept of a tapered core is not new to bone screw technology. At present, at least one other legally marketed bone screw features a tapered core design and variable thread geometry. Howmedica's Fully Threaded Alta Cancellous Bone Screw also possesses a tapered core and variable thread geometry, although it achieves its tapered core by using standard thread cutting techniques.

The use of standard thread cutting techniques while incorporating a taper into the minor diameter of the screw results in a thickening of the thread crest. In clinical application, as the thread thickness increases, more bone must be displaced by the thread form and less bone is contained between the threads. By increasing the thread angle along the length of the screw, the Varifix design keeps the thread crest constant.

The Varifix Bone Screw thus possesses a variable thread angle along the length of the screw while holding the thread crest dimension constant, whereas the Alta Cancellous Bone Screw holds the thread angle constant along the length of the screw while varying the thread crest dimension. In its intended use, this new design potentially reduces the amount of bone displaced by the thread form and increases the amount of bone between the threads. This new design possesses the advantages of previous tapered minor diameter screw designs, while potentially reducing the insertion torque applied during clinical application of the screw

Based on the design rationale, use of well known materials, feature comparisons, indications for use, and engineering analysis, National Medical Specialty believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent in safety and effectiveness to existing legally marketed orthopaedic bone screws.

Table 3 on the following page presents comparative information for the Varifix Bone Screw and predicate bone screws marketed by Synthes and Howmedica, including the previously discussed Howmedica Alta Fully Threaded Bone Screw.

TABLE 3: Summary of Relevant Comparative Information

	Varifix Bone Screw	**Synthes Bone Screw** *(standard bone screw)*	**Howmedica Fracture Fixation Appliance** *(standard bone screw)*	**Howmedica Fully Threaded Alta Cancellous Bone Screw**
SCREW DESIGN:				
Tapped/Self-Tapping	Self-tapping	Tapped Hole	Self-tapping	Self-tapping
Reported Screw Length	Includes tip and head	Includes tip and head	Includes tip and head	Includes tip and head
Head Style	Hex Recess Socket	Hex Recess Socket	Hex Recess Socket	**Torx Recess Socket**
Shank	No	Yes and No	No	No
Thread Depth	**Variable**	Constant	Constant	**Variable**
Crest Dimension	Constant	Constant	Constant	**Variable**
Core Geometry	**Tapered**	Cylindrical	Cylindrical	**Tapered**
Thread Angle	**Variable**	Constant	Constant	Constant
Thread Shape	Buttress	Buttress	Buttress	**Non-standard**
Thread Pitch	Constant	Constant	Constant	Constant
MATERIALS:	Stainless Steel (ASTM F138)	Stainless Steel (ASTM F138)	Stainless Steel (ASTM F138)	Stainless Steel (ASTM F138)
STERILIZATION:	Steam	Steam	Steam	Steam
INTENDED USE:	All screws have the same intended use as fracture fixation devices.			

REFERENCES

All relevant information was obtained from Synthes AO/ASIF and Howmedica product catalogs.