510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:	SeaSpine, Inc. Contact: Kirt Stephenson 6276 River Crest Drive, Suite E Riverside, CA 92507-0754 Phone: 909-656-4850 Fax: 909-656-5530
Company Registration Number:	2032593
Submission Correspondent:	The Regulatory Affairs Company Contact: Diana Smith 727 Park Boulevard San Diego, CA 92101 Phone: 619-251-9132 Fax: 619-696-9883
Date Summary Prepared:	July 11, 2003
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (Class II) - KWQ 888-3060
Common/Usual Name:	Anterior Cervical Plate System and Instruments
Device Trade Name:	Sonoma™ Anterior Cervical Plate System

The primary devices used for comparison in this summary are Synthes' *Synthes Anterior Cervical Vertebrae Plates* and Howmedica Osteonics' *Reflex Anterior Cervical Plate System.*

1. **Intended Use:** (The statements of intended use are identical.)

The intended use of the Sonoma anterior cervical plates and their components is substantially equivalent to the intended use of the predicate devices. The Sonoma Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from C_2 to T_1 during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

2. Description:

The Sonoma Anterior Cervical Plate System includes titanium alloy anterior cervical plates and bone screws. The anterior cervical plates will be available in levels 1 through 4 and in 31 sizes that range from 12.0 to 84.0mm. The cervical plate bone screws will be offered in 4.0mm and 4.5mm fixed and variable angles and come in sizes ranging from 10mm to 20mm. All screws will also be available with a single or double lead. The product is supplied "NON-STERILE" and must be sterilized prior to use

The Sonoma Anterior Cervical Plate System also utilizes a variety of instruments to assist in placement of the devices. These instruments include a cervical awl, removal tool, tap, plate bender, driver, standard fixed/variable drill guide, and drills. The instruments will be fabricated from stainless steel and Radel. The product is supplied "NON-STERILE" and must be sterilized prior to use.

3. Technological Characteristics:

The Sonoma Anterior Cervical Plate System has substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, and material.

4. Comparison Analysis:

The overall design of the Sonoma Anterior Cervical Plate System is substantially equivalent to the predicate devices. See **Table 1** below for a comparison of the Sonoma Anterior Cervical Plate System and the predicate devices.

PREDICATE DEVICE COMPARISON SUMMARY TABLE				
Feature	**Sonoma ACPS**	**Synthes ACVP**	**Reflex ACPS**	**Substantialy Equivalent**
Intended Use	See Insert	Similar	Similar	Yes
Indications for Use	See Insert	Similar	Similar	Yes
Design	Level 1-4 plates with fixed and variable screws	Similar	Similar	Yes
Sizes	See prints	Similar	Similar	Yes
Material	Titanium	Same	Same	Yes
Sterile	Non-sterile	Same	Same	Yes
Mechanical Strength	See test results	Similar	Similar	Yes

Table 1: Summary of Design Comparison

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter:

A financial certification and/or disclosure statement is not needed for this submission as no clinical studies have been undertaken in regards to the products under consideration.

(j) For submission claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990: and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III Summary). The 510(K) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (Class III Certification), as described in Sec. 807.94.

A class III Certification and Summary is not needed for this submission as the products under consideration are class II.

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

A ***Premarket Notification Truthful and Accurate Statement*** is included on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

SeaSpine, Inc.
C/o Ms. Diana Smith
The Regulatory Affairs Company
727 Park Boulevard
San Diego, CA 92101

Re: K032368
Trade/Device Name: Sonoma™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: July 29, 2003
Received: August 1, 2003

Dear Ms. Smith:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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 Millerson

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

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Sonoma™ Anterior Cervical Plate System

The Sonoma Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from C_2 to T_1 during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

for Mark N Milhem

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

510(k) Number K032368

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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