



FEB 26 2001

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Michael A. Baker
President & CEO
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086-2916

Re: AthroCare Orthopedic Electrosurgery
System (Perc-D, Perc-DL), K992581;
K000044; (CAPSure, CAPS X), K001302

Dear Mr. Baker:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your web site at the internet address: <http://www.arthrocare.com> for the ArthroCare Orthopedic Electrosurgery System. Some of the components of this system include the Perc-D and Perc-DL Spine Wands and the CAPSure and CAPS X Spine Wands. These products are manufactured by ArthroCare Corporation (ArthroCare) and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The ArthroCare Orthopedic Electrosurgery System is composed of an electrosurgical generator, a reusable cable, and disposable wands (Perc-D, Perc-DL, and CAPSure and CAPS X). The ArthroCare Orthopedic Electrosurgery System (ArthroCare System) is intended for resection, ablation and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

Your web site contains numerous claims for the ArthroCare Electrosurgery System that have not been cleared by the agency i.e., cervical and lumbar intervertebral disc excision, iliac crest exposure, scar tissue removal, treatment of contained herniated discs, promoting the volumetric reduction of contained herniated discs, treating axial and radicular symptoms caused by herniated or compressed discs, providing shrinkage of collagen with the disc, preventing chondrocyte damage, and limiting damage to the nerve root. Representative statements from your web site making these claims include, but are not limited to the following:

- The ArthroCare Spine Surgery System is being used for soft tissue removal in surgical procedures that may include cervical and lumbar intervertebral disc excision, iliac crest exposure, and scar tissue removal
- ArthroCare Spine has introduced two products for volumetric soft tissue removal in the nucleus to treat contained herniated discs. These products, the Perc-D and Perc-DL, use coblation to ablate tissue via a low temperature, molecular dissociation process to create small channels within the disc
- These products when used in conjunction with a procedure called Nucleoplasty, may promote volumetric reduction of contained herniated discs

Your press release of September 12, 2000 appearing on your web site contains the following claims regarding the Perc-D and Perc-DL:

- ...Treatment for contained herniated spinal discs. These products, the Perc-D and Perc-DL disposable surgical devices, which are used in a procedure called Nucleoplasty, combine the company's coblation technology with thermal energy to partially remove and treat the nucleus of affected discs
- Using the Perc-D devices in nucleoplasty procedures, surgeons and spine specialists now have a method to treat axial and radicular symptoms caused by herniated or compressed discs without resorting to open surgical therapies
- Thermal energy is applied while withdrawing the device to coagulate the area around the channel and provide shrinkage of the collagen within the disc
- ...The precision and control of the Perc-D products confine treatment to the nucleus limiting the possibility of inadvertent damage to the nerve root

In a January 22, 2001 telephone conversation with [redacted] Vice-President, Quality Assurance and Regulatory Affairs, [redacted] confirmed that submission K992581 related to the Perc-D and Perc-DL devices. However, the Office of Device Evaluation (ODE) can find no references to the Perc-D or to the Perc-DL in the 510(k) submission for K992581. Please clarify the regulatory status of these devices.

Claims for the CAPSure and CAPS X wands include claims that they can effectively reduce tissue shrinkage:

- Thermal Arthrowands: enhanced tissue shrinkage...The Thermal CAPS arthrowands offer ultimate versatility and control to address a wide range of shrinkage needs effectively and simply. For cases when a conservative approach is best, the CAPS X

wand provides thermal treatments to a depth of 1.0 mm. When maximum shrinkage is needed, the CAPSure Wands with patented PORT technology provide thermal penetration to a depth of 2.0 mm

- CAPSure: Catalog No. A 1730-01 and A 1830-01 Intended Use: Tissue Shrinkage; CAPS X Catalog No. A 1630-01 Intended Use: Tissue Shrinkage
- Under the web site heading titled, Thermal Treatments... For applications where the goal is to shrink tissue without ablating, radiofrequency (RF) energy delivery is reduced to achieve a sub-Coblation mode for restrictive heating
- Under the web site heading titled, Arthroscopic Applications... Arthrocare's Arthrowands are the most comprehensive range of radiofrequency (RF) surgical tools for Arthroscopic soft tissue removal, dissection, and shrinkage

Additionally, tissue shrinkage claims are also made in Arthrocare's Technique instruction guide titled, "Capsular Shrinkage Technical Guide. Using Arthrocare CAPS X Arthrowand" written by Eugene M. Wolf, M.D., June 1998.

All of the above claims narrow the intended use from a general clearance to a more specific clearance. On January 10, 1997, FDA published a guidance document titled, Deciding When to Submit a 510(k) for a Change to an Existing Device (copy enclosed). We believe item A1 from flowchart A, i.e., "Does the change affect the indications for use" directly applies to the above claims. The need for a new 510(k) for the above claims is also described in the regulations under 21 CFR 807.81(a)(3)(ii) which state that a major modification in the intended use of the device requires the submission of a new 510(k).

The Perc-D, Perc-DL, CAPSure, and CAPS X devices are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a), or approved applications for Investigational Device Exemptions (IDE's) under section 520(g).

The Perc-D, Perc-DL, CAPSure, and CAPX devices are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use(s) of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Perc-D, Perc-DL, CAPSure, and CAPS X devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable

regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

Deciding When to Submit a 510(k) for a Change to an Existing Device