XOMED® K990793

OCT 22 1999

510(k) Summary
EMG Monitor

1.0 Date Prepared
March 5, 1999

2.0 Submitter (Contact)
David Timlin
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name

Proprietary Name:	AccuGuide Muscle Injection Monitor (The product's trade name has not been finalized and may be changed at a later date.)
Common Name(s):	Electromyographic (EMG) Monitor, Muscle locator
Classification Name:	Electromyographic (EMG) Monitor Nerve locator / stimulator,

4.0 Device Classification
Current NIM EMG monitors manufactured by Xomed were classified via K934426 and K982595 as follows:

Nerve locator / stimulator
Procode 77 ENT Class II ; 21 CFR 874.1820

Electromyographic (EMG) Monitor
Procode 89 CAB Class II ; 21 CFR 890.1375

The accessory, disposable, injector needle electrodes that are provided with the system could be classified as follows:

Electromyograph needle electrode
Procode 89 IKT Class II; 21 CFR 890.1385

Needle electrode
Procode 89 GXZ Class II; 21 CFR 882.1350

REVISED 10/19/99

5.0 Device Description

The proposed EMG monitoring system is composed of a small, handheld monitor, a reusable patient interface cable and a disposable injector needle electrode. Commercially available surface electrodes, to act as references, may or may not be provided with the proposed system as these are readily available at the point of use. There are six touchpad keys on the front console – ON/OFF, Sensitivity, Battery Check, Volume Up, Volume Down, and Mute. The software of the proposed EMG monitoring system interprets console key presses from the user and performs the action associated with that key.

6.0 Intended Use

The subject monitor detects bioelectrical signals from muscles for the purpose of guiding injections into the muscles identified. Although the monitor is indicated for guidance of any muscle-specific injection, it is typically used for injections into muscles of the head and neck. This includes botulinum toxin injections of facial and laryngeal muscles.

7.0 Substantial Equivalence

Currently marketed EMG monitors are used to locate specific target muscles prior to making an injection of a solution or medication, such as botulinum toxin. Typically, the currently marketed monitors are large and contain features that are not necessary for merely locating target muscles. A simple raw EMG monitor is all that is needed.

Allergan, Inc. is currently marketing the BOTOX® Injection Amplifier, a simple EMG monitor specifically intended for guiding muscle specific injections. The 510k for the monitor is believed to be K900098, and the needle electrodes sold with this system are manufactured by TECA Corporation as cleared via K973444. The Xomed EMG monitoring system proposed in this 510k, a hand-held, battery-operated EMG monitor with injection needle electrodes, is equivalent to the Allergan BOTOX® Injection Amplifier and Allergan / TECA Myoject needle electrodes, respectively.

Both systems use identical injection needle electrodes to pick-up EMG from the target muscle, which is then processed by the EMG monitor. As with other commercially available EMG monitors (e.g. Xomed's NIM monitors), both the proposed AccuGuide and predicate Allergan system transform the EMG signal into an audible response. In the case of the proposed AccuGuide monitor, the EMG signal is also transformed into a visible response via an LCD bargraph display. The presence of an appropriate EMG response, in conjunction with a specific muscle movement, confirms the location of the injection needle. Once confirmed, the solution or medication is injected through the injection needle electrode using a standard disposable syringe (not provided with this system).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

Mr. David Timlin
Manager, Regulatory Affairs
XOMED Surgical Products, Inc.
6743 Southpoint Drive, North
Jacksonville, Florida 32216

Re: K990793
Trade Name: Electromyography (EMG) Monitor
Regulatory Class: II
Product Code: GXZ, IKT, CAB
Dated: July 22, 1999
Received: July 26, 1999

Dear Mr. Timlin:

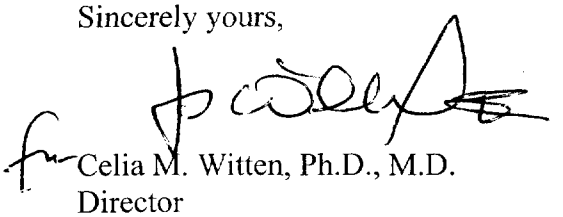
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (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, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: **Electromyography (EMG) Monitor**

Indications for Use:

The subject monitor is intended to detect bioelectrical signals from muscles for the purpose of guiding injections into the muscles identified, including botulinum toxin injections of eye muscles.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990793

Prescription Use X Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)