K002098

NOV 24 2000

1. General information

a. Correspondents to the File
David Ku, M.D., Ph.D.
President and CEO
SaluMedica™

b. Submitter's Name and Address
SaluMedica™, L.L.C.
112 Krog Street
Suite 4
Atlanta, Georgia 30307
Phone: (404) 589-1727
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c. Device Generic Name
Nerve Cuff

d. Device Trade Name
SaluMedica™ Nerve Cuff

e. Equivalent Devices
Fastube™ Nerve Cuff and silicone nerve cuffs

2. Device Description

The Salumedica™ Nerve Cuff with Salubria™ biomaterial is a flexible tubular sheath developed to provide a protective environment for peripheral nerve repair after injury.

The Salubria™ Nerve Cuff is designed to be an interface between the nerve and its bed and to create a conduit for axonal growth across a nerve gap.

The SaluMedica™ Nerve Cuff is available in sizes of 2, 5, and 10 mm inner diameters. Each Nerve Cuff is provided sterile, hydrated in saline for presentation onto the operative field.

3. Intended Use

The SaluMedica™ Nerve Cuff with Salubria™ Biomaterial is intended for use in repair of peripheral nerve discontinuities and where gap closure can be achieved by flexion of the extremity.

4. Non-Clinical Test Summary

Summary of Testing presented in 510(k)

As part of the Pre-market Notification (510(k)) submission, non-clinical evaluation of the SaluMedica™ Nerve Cuff included the following:

a. Biocompatibility Testing
   Testing was completed to verify that the SaluMedica Nerve Cuff with Salubria Biomaterial has acceptable biocompatibility for use as a permanently implanted device.

b. Dimensional Analysis
   Dimensional analysis was completed to verify that the dimensions of the SaluMedica™ Nerve Cuff were within specified tolerances following exposure to electron beam sterilization processing.

c. Compression and Rebound Analysis
   Compression and rebound analysis was completed to verify that the SaluMedica™ Nerve Cuff (1) can withstand compressive forces greater than 0.25N without collapsing, and (2) will re-open following removal of compressive forces sufficient to collapse the nerve cuff.

d. Suture Retention Testing
   Suture retention strength testing was completed to verify that the SaluMedica™ Nerve Cuff has sufficient strength to resist suture pull-out under loads exceeding those anticipated in the intended use environment.

e. Shelf-Life Testing
   Accelerated aging and testing was completed to verify maintenance of functional integrity of the SaluMedica™ Nerve Cuff following accelerated aging equivalent to six months of real-time aging.

f. Evaluation of Nerve Cuff in a Simulated Clinical Environment
   The SaluMedica™ Nerve Cuff was evaluated in the indicated environment to demonstrate that the design of the device meets the needs of the user.

Currently no known FDA cleared nerve cuffs are available for commercial sale. Non-clinical evaluation as outlined above is intended to show that the SaluMedica Nerve Cuff meets the device design criteria based on the aide of information gained from medical professionals, literature reviews, and discussions with FDA reviewers. The device conforms to dimensional specifications, remains open during implantation even if compressed, is capable of retaining suture material, and has a shelf life of six months based on accelerated aging testing. Further, evaluation of the SaluMedica Nerve Cuff in a Simulated Clinical Environment establishes that the device meets the needs of the patient and physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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David N. Ku, M.D., Ph.D.
President and CEO
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112 Krog Street, Suite 4
Atlanta, Georgia 30307

Re: K002098
Trade Name: SaluMedica™ Nerve Cuff
Regulatory Class: II
Product Code: JXI
Dated: September 22, 2000
Received: September 25, 2000

Dear Dr. Ku:

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,

for Mark N Milhern

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

K002098

510(k) NUMBER: K002098

DEVICE NAME: SaluMedica™ Nerve Cuff

INDICATIONS FOR USE:

Repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002098