K982128

Pilling Weck

OCT 23 1998

510(k) Summary

1. **Submitter Name, Address, and Date of Submission.**

Elizabeth Lazaro
Pilling Weck Surgical
420 Delaware Drive
Fort Washington, PA 19034
Telephone Number (800) 523-6507
Fax Number (800) 332-2308

Contact: Same as above

2. **Name of the Device, Common, Proprietary (if Known), and Classification.**

Classification Name: Tracheostomy Tube and tube cuff

Common Name: Phonation (speaking) Valve

Proprietary Name: Shikani-French Speaking Valve

3. **Identification of the legally marketed device to which the submitter claims equivalence.**

The Shikani-French Speaking Valve is substantially equivalent to the Passy Muir, Willy Rüsch and A&M speaking valves.

4. **Description of the Device.**

The Shikani-French Speaking Valve consists of a plastic outer body and a captured inner ball that forms the check valve. The assembly attaches to the C.L. Jackson Improved Stainless Steel Trachea Tube. Once in place, the valve allows the patient to inhale through the tracheostomy tube and exhale across the vocal chords which facilitates speak.

5. Intended Use of the Device.

The Shikani-French speaking valve is intended to redirect exhaled air over the vocal cords to allow speech in tracheostomized patient.

6. Summary of Technological Characteristics.

The technological characteristics are the same as, or equivalent to, predicate devices by Passy Muir (K944451), Willy Rüsch (K964056), and A&M speaking valves.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 1998

Ms. Betty Lazaro
Regulatory Affairs Associate
Pilling Weck Surgical
Surgical Division
420 Delaware Drive
Fort Washington, PA 19034

Re: K982128
Shikani French Speaking Valve
Regulatory Class: II (Two)
Product Code: JOH
Dated: October 14, 1998
Received: October 15, 1998

Dear Ms. Lazaro:

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 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). 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 requirements, 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) 594-4648. 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" (21CFR 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/dsma/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982128

Device Name: Shikani-French Speaking Valve

Indications for Use:

To allow airflow over the vocal cords for speaking function. To be used only as an attachment to CLJackson improved trachea tubes, manufactured by Pilling Weck Surgical.

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 Cardiovascular, Respiratory, and Neurological Devices

510(k) Number

Prescription Use_____
OR
Over-The-Counter Use_____
(Per 21 CFR 801.109)