

AUG 15 2000

K 993934

VQ CORPORATION



Jennifer Reid Price
President

Michael A. Price
Vice President

E-mail mprice vq@
biostart.org

SECTION 510(k)
SUMMARY OF SAFETY AND EFFECTIVENESS
INFORMATION FOR THE V QUICK PATCH

1. Name and address of device manufacturer submitting 510(k) notification:

VQ Corporation
3130 Highland Avenue, Third Floor
Cincinnati, OH 45219-2374
Telephone: 513-475-6626
Telecopier: 513-385-4348

2. Regulatory Correspondent:

Michael A. Price, Vice President, Regulatory Affairs
VQ Corporation
3130 Highland Avenue, Third Floor
Cincinnati, OH 45219-2374
Telephone: 513-475-6626
Telecopier: 513-385-4348

3. Date summary was prepared: November 17, 1999

4. Name of Device:

- (a) Proprietary Name: V Quick Patch™
(b) Common, usual name: ECG Electrode
(c) Classification Name: Electrocardiograph Electrodes

5. Predicate devices to which VQ is claiming substantial equivalence:

- (i) The device will be marketed as electrocardiograph electrodes with an accessory device for placement of six precordial electrodes for a 12 lead ECG. Under current FDA policy, an accessory device is classified according to the regulatory class of the parent device or the device to which the accessory device will function as an accessory. Accordingly, the V Quick Patch claims substantial equivalence to the parent device, electrocardiograph electrodes for the accessory placement device.
- (ii) The V Quick Patch is substantially equivalent to the K-Snap, Silver/Silver Chloride ECG electrodes of Katecho Inc.; the Fastrace® Tab ECG

Electrodes marketed by ConMed; and, Q Trace marketed by Graphic Controls.

6. Statement of the Purpose for which the V Quick Patch Device will be Recommended:

The V Quick Patch is intended to be used as a twelve lead ECG electrode placement device that allows six precordial electrocardiograph electrodes to be placed rapidly on the chest of a human being. The remaining four limb lead electrodes are placed manually. This intended use is well understood and does not represent a new or unexpected mode of operation for the users.

7. Device Description:

The V Quick Patch™ is a single-use disposable device. It consists of two components. One component is mylar electrode positioning guide. It has pre-cut channels and measurement markings for movement and placement of electrodes. The second component consists of ten post-style Ag/AgCl ECG electrodes six of which are pre-mounted into the channels of the mylar positioning guide. The electrodes are identical to other post-style Ag/AgCl electrodes currently on the market except for a raised mylar disc affixed to the top of the six precordial electrodes which allows the precordial electrodes to remain attached to the positioning guide and to be moved within the channels of the positioning guide for placement on a patient's chest.

8. Safety and Effectiveness of Device:

The positioning guide component of the device is a 5 mil. natural polyester mylar. It is not intended to contact the skin surface because the electrode that it places will be in contact with the skin surface. There may, however, be short term incidental contact from time to time during usage of the device. The electrode component of the device is standard post-style AG/AGCL electrodes with a mylar positioning disc affixed to the top of the six precordial lead electrodes so that they will remain in and move throughout the channel of the positioning guide.

The device underwent clinical testing at the University of Cincinnati. One study involved 100 patients who suffered from cardiac or pulmonary disease. The study found that the V Quick patch was as safe and as effective as the standard precordial tab-style electrodes. Specifically, the study found that the V Quick patch electrodes produced electrocardiograms (ECG's) that were equivalent to ECG's produced by the standard precordial tab-style electrode. The study further found no skin reaction or loss of skin integrity from using the V Quick patch on patients in the study.

9. Substantial Equivalence Comparison

(i) General Description:

Current practice is for a health care practitioner to manually place ten separate electrodes to create the traditional 12 lead ECG electrode recording. The patch allows a rapid placement of the six precordial electrodes in a manner that reduces placement time and improves placement accuracy. The accuracy and efficacy for 12-lead electrocardiograms of the V Quick Patch in comparison to manual placement was evaluated in a study involving 100 patients with cardiac or pulmonary disease. The study demonstrated that use of the V Quick Patch provided the same quality of electrocardiograms as the standard manually and separately placed precordial electrodes.

(ii) Substantial Equivalence Comparison Matrix Comparing Primary Features of Currently Marketed Electrodes to the V Quick Patch™:

<u>Primary Features</u>	<u>Currently Marketed Electrode</u>	<u>V Quick Patch Electrodes</u>
Sensing Element	Ag/AgCl coated plastic sensing element	Same
Conductive Gel that contacts skin	Wet gel or dry adhesive	Wet gel
Adhesive disc that adheres to skin surface	Compliant polyethylene foam	Compliant polyethylene foam
Adhesive disc size	2.25"	2.0"
Protective Cap (release liner)	Release coated polystyrene film	Release coated polystyrene film
Total Weight (g)	Approx. 1.96 g.	Approx. 4.05 g.
Adhesive on disc	Medical grade acrylic	Medical grade acrylic
Placement of Electrode	Individually place each electrode in position for lead	Six precordial electrodes are placed with mylar positioning guides. Four limb lead electrodes placed manually.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2000

Michael A. Price
Regulatory Affairs, Vice President
VQ Corporation
3130 Highland Avenue, Third Floor
Cincinnati, OH 45219-2374

Re: K993934
V Quick Patch
Regulatory Class: II (two)
Product Code: DRX
Dated: May 16, 2000
Received: May 17, 2000

Dear Mr. Price:

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 (Pre-market 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 or

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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,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993934

Device Name: V Quick Patch

Indications For Use:

The V Quick Patch System is intended to be used as an electrocardiograph electrode and a placement device for the placement of electrocardiograph electrodes.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Markus
Division of Cardiovascular & Respiratory Devices
510(k) Number K993934