

OCT 11 2005

**Section II**

K052495

**Summary of Safety and Effectiveness  
(as required by 21 CFR 807.92)**

**Atrilaze™ Malleable S-2 Disposable Probe**

|                   |  |                 |  |
|-------------------|--|-----------------|--|
| <b>Submitter:</b> | MedicalCV, Inc.<br>9725 South Robert Trail<br>Inver Grove Heights, MN 55077<br>USA | <b>Contact:</b> | Denny Steger<br>V.P. RA/QA<br>Phone: 651 452 3000<br>Fax: 651 452 4948 |
|-------------------|--|-----------------|--|

|                         |                 |                             |                                       |
|-------------------------|-----------------|-----------------------------|---------------------------------------|
| <b>Date of Summary:</b> | August 23, 2005 | <b>Classification Name:</b> | Laser Instrument,<br>Surgical Powered |
|-------------------------|-----------------|-----------------------------|---------------------------------------|

|                     |                           |                    |   |
|---------------------|---------------------------|--------------------|---|
| <b>Common Name:</b> | Surgical Laser Instrument | <b>Proprietary</b> | Atrilaze™ Malleable<br>S-2 Disposable Probe |
|---------------------|---------------------------|--------------------|---|

**Description of Device:** The Atrilaze Malleable S-2 Disposable Probe is used with the Atrilaze™ Surgical Ablation System which consists of a generator designed for the delivery of 810nm laser light and a hand held fiber optic light delivery device (probe) fitted with a standard SMA 905 connector at the proximal end. The system may be used in conjunction with surgical treatment for hemostasis, incision, ablation, coagulation and vaporization of tissue as required by the clinician.

**Statement of Intended Use:** The stated intended use of the Atrilaze Malleable S-2 Disposable Probe is the same as the MedicalCV Atrilaze™ Surgical Ablation System. It is indicated for the delivery of 810nm laser light to soft tissue to include cardiac tissue, during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation or coagulation of soft tissue.

**Warning:** The Atrilaze Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

**Technological Comparison:** The Atrilaze Malleable S-2 Disposable Probe is the same as that of the existing Non-Malleable Disposable Probe that was granted market clearance under K040744. The fiber optic delivery system (probe) is coupled to the laser via an SMA 905 connector to deliver laser radiation to the target tissue(s). For purposes of this submission, the Atrilaze Malleable S-2 Disposable Probe was compared to the following predicate device(s):

- MedicalCV, Inc. Non-Malleable Disposable Probe (K040744)
- CardioFocus, Inc. Malleable Surgical Lightstic 180 (K013901)

**Testing:** Results of biocompatibility testing support statement that the material change from stainless steel to nitinol had no impact on previously gathered test results (K040744). The probe is non-toxic, non-hemolytic, and non-pyrogenic. All biocompatibility testing was conducted under Good Laboratory Practices per 21 CFR Part 58.

Performance testing for the Atrilaze Malleable S-2 Disposable Probe included compliance to manufacturing specifications for Power Output, Tip Pull-Off, Pressure and Flow for the fiber optic light delivery device. Testing demonstrated that the Atrilaze Malleable S-2 Disposable Probe is substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 21 2008

MedicalCV, Inc.  
c/o Mr. Denny Steger  
Vice President Regulatory Affairs/Quality Assurance  
9725 South Robert Trail  
Inver Grove Heights, MN 55077-4424

Re: K052495  
Trade/Device Name: Atrilaze™ Malleable Ablation Probe  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general  
and plastic surgery and in dermatology  
Regulatory Class: II (two)  
Product Code: OLC, GEX  
Dated: September 9, 2005  
Received: September 12, 2005

Dear Mr. Steger:

This letter corrects our substantially equivalent letter of October 11, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indications for Use Statement

510(K) Number: K052495

Device Name: Atrilaze™ Malleable Ablation Probe

**Indications for Use:** The MedicalCV, Inc. Atrilaze™ Surgical Ablation System is indicated for delivery of 810nm laser light to soft tissue to include cardiac tissue during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation, or coagulation of soft tissue.

**Warning:** The Atrilaze™ Surgical Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Juliane Inelump*  
**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

510(k) Number K052495