

VeriCor® Reduces Heart Failure Outcomes & Costs Dramatically

Heart Failure Is a Major Human & Financial Problem In US. With 5 million patients known to have heart failure, 60 million at-risk for heart failure, 300,000 deaths, 1 million hospitalizations and \$39 billion in care-costs a year, heart failure is indeed a major human and financial problem in the U.S. Results of a recent study show that a new monitor could control heart failure hospitalizations, deaths and costs in the U.S.

VeriCor® Monitor Could Control Heart Failure Outcomes & Costs in U.S.

- 1. Only Noninvasive Monitor.** VeriCor® is the only noninvasive ICU-caliber monitor.
- 2. Only FDA-Cleared Monitor.** Only the VeriCor® monitor has been cleared by the U.S. FDA.
- 3. Clinical Assessment v. VeriCor® Monitor.** A 1-year randomized study showed 5.5 more hospitalizations with clinical assessment than with the VeriCor® monitor.

Table 1. Hospitalizations in 12 Months

	Months	1	2	3	4	5	6	7	8	9	10	11	12	Total
Clinical Assessment	Hospitalizations	5	2	3	3	1	0	3	0	1	2	2	0	22
VeriCor® Monitor	Hospitalizations	0	0	0	0	1	0	0	1	1	0	0	1	4

Comment. 50 patients hospitalized for heart failure were randomized to treatment guided by clinical assessment or by the VeriCor® monitor. Patients were followed for 12 months after discharge and hospitalizations were documented each month as shown in Table 1.

In the 12 follow-up months, 22 (85%) of the 26 hospitalizations were in patients with treatment guided by clinical assessment while only 4 (15%) hospitalizations occurred in patients with treatment guided by the VeriCor® monitor.

Heart Failure Deaths & Costs Also Decreased. More than 80% of care-costs in the study were consumed by patients managed by clinical assessment. In addition, 75% of the deaths that occurred in the follow-up period were in patients managed by clinical assessment.

Conclusions.

- 1. Clinical Assessment Unacceptable.** Clinical assessment alone is no longer acceptable.
- 2. VeriCor® Monitor Ideal.** By overcoming the serious limitations of clinical assessment, the VeriCor® monitor showed it is ideal for the management of heart failure patients.
- 3. Human & Financial Benefits of VeriCor®** Earlier publications by CVP Diagnostics indicated that the VeriCor® monitor could prevent more than 80% (800,000) of heart failure hospitalizations while also reducing care-costs by 80%, i.e., \$31.2 billion.
- 4. Evidence Shows VeriCor® Superior to Clinical Assessment.** The new VeriCor® study results (Table 1) provide statistically significant ($p < 0.01$) evidence showing the VeriCor® monitor is more effective in reducing heart failure hospitalizations and costs. Also of major importance, the VeriCor® monitor reduced heart failure deaths by more than 65%.
- 5. Human & Financial Benefits of VeriCor® Management for Heart Failure in U.S.**

The table below shows outcomes and costs “NOW” and after reductions of 50% & 65-80%.

	NOW	50% Reductions	65-80% Reductions
Hospitalizations	1M/Year	500K/Year*	800K/Year (80%)
Deaths	300K/Year	150K/Year	195K/Year (65%)
Costs	\$39B/Year	\$19.5B/Year	\$31.2B/Year (80%)

*K stands for thousands

Conclusion. Treatment guided by monitoring could reduce hospitalizations by 500K to 800K, deaths by 150K to 195K and costs by \$19.5 billion to \$31.2 billion a year.

6. Major Reductions in Outcomes & Costs in US States. Comprehensive use of the VeriCor® monitor could prevent 4,800 deaths in 12 states & 8,000 deaths in 7 states and prevent 15,000 hospitalizations in 10 states and 20,000 in 8 states. Costs could be reduced by \$300 million in 19 states and \$1 billion in 4 states.

7. Monitoring Revenues to CVP Diagnostics. Chaired Professor of Biomedical Engineering at Harvard-MIT Division of Health Sciences & Technology projects that VeriCor® monitoring revenues to CVP Diagnostics in 5 years will be \$30 billion a year.

Breakthrough Advances in Heart Failure Care

New VeriCor® Monitor Could Control Heart Failure in US in 5 to 8 Years

Background. In addition to 300,000 deaths and 1 million hospitalizations a year, annual care-costs for heart failure patients reached \$39 billion in 2008. The new noninvasive VeriCor® monitor showed that the “gold standard” for heart failure care, clinical assessment, is ineffective and leads to more than 80% of hospitalizations and care-costs and more than 60% of heart failure deaths each year.

More importantly, in a randomized comparison, there were 22 hospitalizations in the 1-year follow-up in patients managed by Clinical Assessment and only 4 in patients managed by VeriCor®. In addition, costs were nearly 6 times higher and deaths were 3 times higher in patients managed by clinical assessment.

I. Achievements of CVP Diagnostics & VeriCor® Monitor 2004-2009

1. 2004. FDA Cleared the VeriCor® Monitor to Market in 2004.

2. 2006. VeriCor® Proves Clinical Assessment Is Ineffective. The VeriCor® monitor measured LVEDP in 115 “stable” heart failure patients and found that 74 (64%) had abnormally elevated LVEDPs that led to 31 (94%) of 33 hospitalizations and 8 (73%) of 11 deaths in the subsequent 12 months. In addition, more than 90% of \$462,000 in care-costs in this population for 12 months were consumed by the care of patients with abnormally elevated LVEDPs. The authors concluded that treatment guided by the VeriCor® monitor may be needed if heart failure care is to be optimized.

3. 2009. VeriCor® Reduces Heart Failure Outcomes & Costs Dramatically. As noted above, a head-to-head comparison between clinical assessment and the VeriCor® monitor showed that there were 5.5 times more hospitalizations (22) in 12 months in the clinical assessment group than in the VeriCor® group.

In addition, deaths were reduced by more than 65% and care-costs were reduced by more than 80% in patients managed by the VeriCor® monitor.

II. Potential Human & Financial Benefits of VeriCor® Monitor Annually In U.S.

The VeriCor® Monitor Could Reduce Heart Failure Outcomes & Costs In U.S. By 50 to 80% With 300,000 annual deaths, 1 million hospitalizations and \$39 billion in care-costs a year in the U.S., a 50% reduction in each would be expected to prevent 150,000 deaths and 500,000 hospitalizations while reducing care-costs to \$19.5 billion a year. VeriCor® study results to date indicate, as described above, that reductions in heart failure outcomes and costs with the VeriCor® could be considerably higher.

III. Potential Reductions in Outcomes & Costs Will Drive Monitoring in US

Comprehensive VeriCor® Monitoring Could Prevent 70-80% of Heart Failure Outcomes & Care-Costs. Every month in the U.S., there are 25,000 heart failure deaths, 16 to 18,000 of which could be prevented by treatment guided by comprehensive monitoring. In addition, more than 65,000 of the 83,000 hospitalizations and \$ 1.5 billion of the \$2.2 billion monthly care-costs could be prevented by comprehensive monitoring.

Supplementing treatment guided by clinical assessment with treatment guided by hemodynamic monitoring is no longer an option, it is an urgent necessity.

IV. Annual Monitoring Revenues to CVP at Full Market Penetration

At full market penetration, annual revenues to CVP Diagnostics from community-based markets are expected to be \$13.8 billion, from home monitoring \$30 billion a year and from the new VeriCor® Hybrid Monitors, \$43.5 billion a year, bringing total annual monitoring revenues to CVP Diagnostics at full market penetration to \$87.3 billion a year.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Re: K031327
Trade Name: VeriCor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: 74 DXN
Dated: March 31, 2004
Received: March 31, 2004

Dear Dr. Athey:

This letter corrects our substantially equivalent letter of May 12, 2004 regarding the classification of the subject device.

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](#).

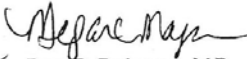
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 and additionally Part 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

for 
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure