Dear Circulatory System Devices Panel:

I'm writing to ask you to tell F.D.A. to approve the Guardian System, mainly because it Save My Life Several Time.

[redacted] my heart doctor, told me about Angel Med. I soon talk to [redacted] & her husband [redacted] they Carely went over the init out about Angel med. I wes more than happy to do the Clinical Trail.

I went 6 month with the divice turn off, then 6 month on. I consently had Chest pain, Weakness, & numbness in my left arm, I had 4 Stem put in my heart R.C.A. and this year a Week before Changing 4 By-Pass in my heart.

My divice Save me 3 to Four time. Once I was Exercising at Army time Fitness Just walking on threadmill my Alarm and the pain in my chest to me to go to hospital by Emergency Service, (911)

My Chest Exray & E.K.G. show nothing Worng, Dr inform them what it show. That Started the Seard of Surgery.

The Second time I jist got up from Sit, watching T.V. Call 911, at hospital they install another Stem in my heart Back Side. The third time was the Big one, if I didn't have The Angel Med they would had found me dead in the yard as I was push mowing around my house. The funny thing was I felt good, The Angel Med Said all 911, That when I had the R.C.A.

All the nurse at North Oak took a class from me on how the Devise Work

Yust as before EKG & Chest exray was Fine.

A week before Thanksgiving off it went again, They took Vein out left Leg, did Thee Chambers, and a Left C.A. to ~~Lat~~ Last Chamber.

I want to Tell you it Work & I did it, to help other paitent & my further grandKid & I would do it all over again.

God Bless theis Devise.

I never had any trouble install it or replace the Battery in this Device.

I truely can said this is a life Saving Device and to be approve so other patients & their Doctor will have it available, just think how many life could had been save if they had this device ten year ago.

Thank you for taking time to read my Letter & I hope for the next heart patient they too can have this Device

[redacted]

DATE [redacted]

RE: March 16, 2016, Meeting of the Circulatory System Devices Panel

Dear Circulatory System Devices Panel:

I am writing to ask you to tell FDA to approve the Guardian System.

I became involved in this study o[redacted] At the time I was having serious heart issues that involved having a stents placed every 4 months. When asked if I would join this study at th[redacted] [redacted] I agreed because I realized that in my case, any advanced warning I could get of a potential heart attack could be the difference between life and death. This device has given both my family and I a great deal of comfort. As a[redacted] I am very active and sometimes push the limit of what a person with my history should. I may need to sit and catch my breath sometimes, but I know that I'll be OK because the device has not gone off.

Fortunately, since receiving this device my heart was able to create new pathways for the blood flow, so I have never had the device alarm me to an issue, but know of people who have been saved due to the early warning.

There has not been a single day since receiving my device that I have regretted the decision. I have had no complications through initial installation, and two battery changes.

I believe this device is a great lifesaving tool that will be beneficial for generations to come. Please approve this device so that others with serious heart conditions can enjoy life with the same assurance my family and I feel.

Thank you for your consideration.

Sincerely,

[redacted]

February 19, 2016

RE: March 16, 2016, Meeting of the Circulatory System Devices Panel

Dear Circulatory System Devices Panel:

I am writing to ask you to tell FDA to approve the Guardian System.

I am a patient in the clinical trial of the Guardian System. I became aware of the trial shortly after I suffered a STEMI event in [redacted] I decided to participate because, frankly, I was scared. Having "lived to tell the story", the STEMI event taught me one valuable lesson – medical response time can make the difference between life and death. The Guardian System offered the potential to provide an early warning system in case this ever happened to me again.

My heart attack happened on a cruise ship that luckily had just docked at the end of our journey. The ship's medical staff were called to my aid within four minutes. They stabilized me in about 30 minutes and transported me to a hospital only 6 minutes away. I received emergency treatment and at the end of the day, the cardiologist told me I was lucky to survive. 24 hours earlier I was hiking in the jungles of Belize, about 2 hours from any form of medical aid. It's not hard to imagine my outcome would not have been so good if my heart event happened there.

If the Guardian System proves to be effective through this study, it will offer two invaluable benefits. First, early detection of a heart attack and reduced time to medical treatment will save lives. Second, the device offers a peace of mind that is very reassuring to cardiac patients. The emotional impact of having lived through a heart attack can be frightening. The Guardian System provides a reassurance that helps patients return to "normal life".

I was in the control group, so my device wasn't activated at first. This was disappointing, but I knew it was only a short term setback. The only negative experience I had was that recovery from the implant surgery was a little more difficult than I anticipated. I had inflammation and pain more than a week after, and suffered a loss of strength in my shoulder for several months. I assume future versions might be physically smaller and cause less discomfort. Even with these issues, I would do it again "in a heart beat"!

This device is a game changer. Please approve it so other patients can have the same protection and reassurance I have come to appreciate. Thank you for your consideration.

Sincerely,

[redacted]

[redacted]

February 18, 2016

Dr. Stephen Ostroff
Acting Commissioner
FDA
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Submission for February 18, 2016, Meeting of the Circulatory System Devices Panel

Dear Dr. Stephen Ostroff:

I want to express my support for the AngelMed Guardian System. I have been an investigator in the [redacted] for the past four years. I treated 29 patients and achieved the following results: brought high risk patients into ER before STEMI/NSTEMI occurred and allowed for non-emergent procedures or primary interventions. It also allowed people with advanced disease to have peace of mind when episodes of angina that would normally bring them to the ER did not trigger an alarm and allowed them to receive NTG and meds at home with resolution of symptoms without the fear of an impending MI.

I have treated cardiac patients for more than thirty years and have specialized in interventional cardiology.
I feel that the Angel-med device addresses an unmet need among patients as it may alert them to the onset of coronary occlusion, especially in the absence of recognizable symptoms. We have seen this during the trial on more than one occasion in our study subjects.

Thank you for considering my expert opinion as the FDA reviews Angel-Med's application for the Guardian System.

Sincere[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

February 25, 2016

Circulatory System Devices Panel
c/o Dr. Stephen Ostroff.

To Whom It May Concern:

My name is [redacted] I am an [redacted] and [redacted]

I have been aware and excited by the concept of intracardiac ST monitoring and alerting, as pioneered by Angel Medical Systems, for more than 10 years. I am delighted to see this technology in its final stage of PMA approval. I am keenly aware of the large unmet need for a better way to get heart attack patients to arrive in the emergency department for earlier evaluation than is possible with our current standard of care, which requires symptom recognition and action by our patients.

Much progress has been made in the prompt treatment of acute myocardial infarction but the time lost between onset of the infarction and the recognition by the patient is the greatest unmet need.

Acute ST segment changes, such as those detected by the Guardian device, are indicative of total coronary occlusion. I have no doubt that the ability to detect these events and prompt patients to arrive earlier in the natural history of a plaque rupture is an important breakthrough in the treatment of patients with high-risk coronary artery disease.

I am very impressed with the time-to-door data that I have reviewed from the [redacted] study. The ability to get patients with an occlusive coronary event to arrive for evaluation at a 51-minute median occlusion-to-door time is an exceptional result. This early arrival may allow prevention of permanent damage to the myocardium in many cases. Reducing time-to-treatment has been the objective of scores of studies, professional society efforts and will provide substantial benefit to many patients.

The Guardian device will be particularly useful for those patients that are victim to a silent MI. Multiple studies have confirmed that the incidence of silent MI is at least 33%, and with a higher rate in women, diabetics and the elderly. In the absence of physical symptoms, an important way to reduce patient delay and get silent MI patients to seek and obtain appropriate care is to have a continuous monitor that can alert the patient to their coronary occlusion. This is what the Guardian is designed to do.

I urge the Panel to recommend approval of this important technology.

Sincerely,

[redacted]

March 1, 2016

Re: March 16, 2016, Meeting of the Circulatory Systems Devices Panel.

Dear Circulatory Systems Devices Panel

I am writing to ask you to tell the FDA to approve the Guardian System.

In the clinical trial, I was part of the Treatment group. I have to admit that one of the benefits to me of the Device is the peace of mind that it brought not only to me but my wife (caregiver) as well. I experienced no complications with the implant or the procedure to place it.

In great part due to the monitor and the parameters that it watches, I have not had a critical or occlusion event or cardiac crises since it was placed. That is not to say that I have not benefited. There were several circumstances that the "call doctor" warning was enough for me to realize that a heart attack was imminent. Had I not heeded these warnings, I am sure I would have experienced a heart attack or occlusion event.

I am not the best historian, but I do remember that some of the alerts were for STL shifts, I do know that my heart rate did trigger a "See Doctor" alert on several occasions and that there were other abnormalities that we, my medical team and I would not have noticed otherwise.

I have experienced no complications with the implant and am barely aware of it unless the alarm "sounds." When that happens, I am grateful for the warning that it provides.

I have found the study to be interesting and have experienced great relief in knowing that I can be warned before a crisis occurs. The relief that it has brought to my wife and myself is priceless. I am aware that the implant has kept me out of the emergency room and decreased the cost of my healthcare in general. The Doctors on my team can more accurately assess my needs when they have access to the information that the device provides. I know that this would be a boon to anyone who is experiencing or is at risk of having heart attacks. Attached is a creative nonfiction essay about the first of several events where, I believe, the device has saved my life.

It is my experience that this technology can be life-saving, and I urge you to approve it, so other patients and their doctors have it available.

If you have any questions or comments, please do feel free to contact me in any of the ways outlined below.

At your service,

[redacted]

[redacted]

February 29, 2016

RE: March 16, 2016, Meeting of the Circulatory System Devices Panel

Dear Dimitrus Culbreath:

I am writing to support the application of Angel-Med to be approved. I am one of the investigators in the [redacted] have implanted many of these devices. I have found that the implant procedure was very easy with essentially a very similar procedure to implanting a single chamber permanent pacemaker. The underlying principal of the device is very simple as it is designed to detect early ST segment shifts indicative of a myocardial infarction. Many patients do not have chest pain when they have a myocardial infarction or they may have atypical symptoms. Many patients chose to ignore these symptoms and do not seek medical help. By giving the patients vibratory alert that they may be having ischemic symptoms or silent ischemia, it is hoped that they would seek medical help earlier and therefore can be taken to the catheterization laboratory for intervention sooner.

In addition, many patients have noncardiac symptoms such as chest pain or epigastric pain and constantly seek medical help by going to the emergency room or doctors' offices. If they have this device implanted and do not have any alerts associated with these symptoms, they can be assured these symptoms are not cardiac and they do not have to constantly use these resources. Many of the patients that I have implanted say they have peace of mind because they know they have a device that is constantly watching them and that will alert them if they have myocardial ischemia. As a testament to that, the majority of the patients whose battery reached end-of-life has chosen to replace it with another battery and not have the device explanted. They had the choice of going either way and the majority of them chose to have the device reimplanted meaning they are deriving significant psychological benefit from the device being there.

If you have any questions, please do not hesitate to call me.

Thank you.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

29 February 2016

FDA Medical Devices Advisory Committee
Circulatory System Devices Panel
10903 New Hampshire Avenue
WO32 - 5129
Silver Spring, MD 20993-0002

Dear Committee Members:

[redacted] appreciates the opportunity to submit comments to the Circulatory System Devices Panel of the Medical Devices Advisory Committee on the premarket approval application for innovative technologies, such as the AngelMed Guardian device.

[redacted] founded in [redacted] s th[redacted] an[redacted] cardiovascular peer-to-peer support network in the nation. Our 20,000 members provide support to more than 215,000 patients each year and offer monthly support meetings through our 300 chapters. We have members in every state and encounter heart attack patients daily.

[redacted] s the president of [redacted] and is a heart patient who has experienced three open-heart surgeries and a number of other procedures. Additionally, all of her maternal uncles experienced MIs, and three of them died from a second MI.

According to the American Heart Association, 785,000 American have their first heart attack and nearly 470,000 experience a second event each year. Following a heart attack, many patients experience deep and justifiable fear of a subsequent event.

Ironically, it is widely known that people experiencing chest pain wait much too long before seeking medical attention, which means that their outcomes are much worse than they could have been. Further, we know that half or more of all heart attacks are silent or manifest with atypical symptoms. This is a huge problem and a tragic predictor of poor, long-term outcomes for those patients.

A device like the AngelMed Guardian is based on an innovative technology that can alert patients to seek medical attention more quickly, whether their MIs are symptomatic or unrecognizable. This would certainly lead to better outcomes and would address a massive problem for patients who are at high risk for heart attack every year.

We request confirmation of your receipt of this letter, and again, appreciate the opportunity to speak on behalf of heart patients.

Respectfully submitted,

[redacted]

[redacted]

February 22, 2016

Dr. Stephen Ostroff
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Letter for Submission to Advisory Panelists re: March 16, 2016, Meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee

Dear Dr. Stephen Ostroff,

I am a national and international leading interventional cardiologis[redacted] at the[redacted] of Medicine i[redacted]

I have been involved in improving the treatment for patients suffering from heart attacks for 30 years. I have been a major contributor to the implementation and validation of the current standard of care, using angioplasty, for the timely treatment of coronary occlusion in the setting of acute myocardial infarction. I also have been a spokesperson advocating better care for women who suffer from heart attacks and other acute coronary syndromes.

We have a real problem with recognition of heart attacks; patient delays lead to worse outcomes. Men and women, but particularly women, are know to have atypical symptoms for MIs and to wait longer to get to the hospital with an MI, even when they have symptoms. At least 25% of all patients suffer silent MIs, and women are even more likely. For example, the Canto Study of 434,000 patients showed that women have a 39% incidence of silent MI, which is significantly higher than the rate observed for men (29%).

The McSweeney study showed 44% of MI's in women were silent. In a report by Leening of 60,000 MIs in patients over 55, the incidence of silent MI in women was 65%; a frightening statistic. The latest data from the 10 year study by Turkbey, et al presented at AHA 2015 found that 78% of patients with myocardial scars seen in MRI were not identified clinically. Such scarring is known to be predictive of poor long term outcomes. Some of these data are shown below:

Study (Year Published) [Patient notes]	Number of MIs	% Silent MIs
Canto et al. (2000)	434,877	33%
Males	180,922	29%
Females	253,954	39%
Leening (2010) [>55 years of age]	6,305	48% (F=65%; M=37%)
McSweeny (2003) [Females]	515	44%
Turkbey (2015)	146	78%*

*Not recognized by the standard of care

As you may imagine, I have thought long and hard about how to improve heart care for my patients and for women in particular. A monitor that could let the patient know that the pain in their back, or their indigestion was actually a symptom from a blocked coronary artery could be very helpful. Even more important is the critical need to prompt patients to seek medical care when there are no warning symptoms.

The AngelMed Guardian is a first of its kind technology that can alert patients to seek medical attention more quickly whether their MIs are symptomatic or unrecognizable and this can lead to better patient outcomes. In my opinion, this is a technology that is as innovative in the realm of MI detection shifting as was angioplasty for treatment of acute MI. I have reviewed the data from the [redacted] study and believe that the Guardian is safe and performed impressively to meet this unmet need. This device did what it was designed to do - it got patients with occluded coronaries to quickly take action, and to seek medical attention, independent of symptoms.

This technology can help reduce late arrivals and bring asymptomatic patients in for an MI that would otherwise not seek medical care. A post market study can also help further validate that improvements in time-to-door times, *which have not changed in 30 years*, will lead to better outcomes for patients. This important tool can help me take better care of my patients and I support its approval.

Respectfully,

[redacted]