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TELECOPIER:
(202) 429-4912
general@g2w2.com

HENRIETTA WRIGHT
THOMAS G. GHERARDI, P.C.
COUNSEL

December 2, 2003

ELECTRONIC FILING

Ms. Marlene Dortch
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Re: ET Docket No. 03-92
Notification of Ex Parte Presentation

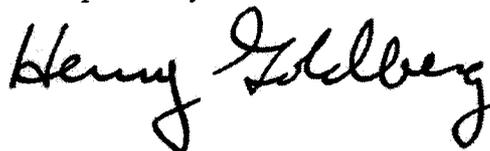
Dear Ms. Dortch:

Today, the undersigned, accompanied by Mark Johnson of Biotronik, Inc. ("Biotronik"), met with the following persons: Sheryl Wilkerson, Legal Advisor to Chairman Powell; Barry Ohlson, Legal Advisor to Commissioner Adelstein; Sam Feder, Legal Advisor to Commissioner Martin; Jennifer Manner, Legal Advisor to Commissioner Abernathy; and Paul Margie, Legal Advisor to Commissioner Capps.

During the meeting, Biotronik urged a grant of its pending request for waiver of the MICS rules without further delay in light of the urgent medical need for Biotronik's implant devices and the lack of any realistic possibility of interference to other users of MICS frequencies. These positions are reflected in Biotronik's filings in the above-referenced proceeding. Copies of the handouts provided to staff members during the meeting are attached hereto.

Please direct questions concerning this matter to the undersigned.

Respectfully submitted,



Henry Goldberg
Attorney for Biotronik, Inc.

Enclosures

cc: Sheryl Wilkerson (by e-mail)
Barry Ohlson (by e-mail)
Sam Feder (by e-mail)
Jennifer Manner (by e-mail)
Paul Margie (by e-mail)
Ed Thomas (by e-mail)
Julius Knapp (by e-mail)
Bruce Romano (by e-mail)

Excerpts of Letters from Physicians

“I have been a physician for many years, and I find [Biotronik’s] technology one of the most powerful I have seen. It is likely to revolutionize the way we manage implanted devices. I have already made several arrhythmia diagnoses, and applied this Biotronik technology to manage successfully patients posing difficult atrial fibrillation problems. This early-intervention capability allows me to see trends that warrant early intervention to prevent a potentially life-threatening cardiac event from occurring. Without this technology the ability to prevent and treat these conditions early is completely lost. Biotronik’s technology is the only system that gives me the information I need for this kind of care.” - **Niraj Varma, M.D., Case Western Reserve University**

“In all my years as an implanter of pacemakers, I find [Biotronik’s] technology the most innovative and useful of any that I have encountered. I have already made several arrhythmia diagnoses that would likely have been missed if not for these periodic transmissions. This early-intervention capability allows me to see trends that warrant early intervention to prevent a potentially life-threatening cardiac event from occurring. Without this technology, the ability to prevent and treat these conditions early is completely lost. Providing diagnosis based on a singular data point is a very difficult but real problem that the medical community faces today. Biotronik’s technology is the only system that gives me the information I need to provide early intervention. I strongly urge you to grant the waiver request immediately so that I can implant monitoring devices into these patients right away. Time is of the essence.” - **Farrell D. Pierson, M.D., West Knoxville Heart, P.C.**

“[Biotronik’s] periodic messaging is the only technology that can provide trend information in real-time, automatically, and wirelessly. Banning this capability leaves the medical community ‘blind’ to these any many other conditions that can benefit from real-time trend reporting. The Order prohibiting this technology from being available blinds us from seeing this critical information and intervening to reduce patient morbidity, increase quality of life, and reduce costs to healthcare.” - **Alistair Fyfe, M.D., The Dallas Heart Group**

Breakthrough technology agreements with Biotronik, Inc., for ICD and pacemaker Home Monitoring technology

Effective December 1, 2003, Premier's CV Committee awarded breakthrough technology agreements to Biotronik, Inc., for their pacemaker with Home Monitoring technology (PP-CA-052) and for their implantable cardioverter defibrillators (ICDs) with Home Monitoring technology (PP-CA-053).

Initially, a physician panel reviewed the data submitted by Biotronik and based on the breakthrough technology recommended the awards. The CV Committee reviewed the recommendation and voted to add Biotronik's breakthrough technology for its pacemaker and ICDs with Home Monitoring technology to the cardiovascular portfolio.

Home Monitoring provides physicians with a completely automated, wireless way of receiving critical information on arrhythmias, therapy delivery, medication effects, and device status. This allows physicians to increase their chances of success by addressing time-sensitive problems long before they become chronic or critical.

Both of these agreements are 24-month multi-source awards with Medtronic USA, Inc. (PP-CA-003A/B) and Guidant Sales Corporation (PP-CA-004A/B). These agreements are preferred agreements and are also part of the Premier Portfolio Plus Program. Completion and execution of a Participating Member Designation Form (PMDf) is required to access pricing other than Tier 1 for both agreements.

Highlights of the Biotronik breakthrough technology agreements include:

- Effective dates December 1, 2003 – November 30, 2005,
- Price protection for the term of the agreement,
- Portfolio Plus/aggregation pricing option,
- IDN local negotiation,
- Bulk Buys, and
- Access for alternate site healthcare facilities.

To view contract details and/or pricing related to this agreement, visit Premier's electronic catalog at <http://www.premierinc.com> or contact Paula Mowbray, Clinical Specialist, at 630.891.4531. For specific product information, visit Biotronik's Web site at <http://biotronikusa.com>.

Be sure to visit Premier's [Cardiovascular Web site](#) for the latest cardiovascular news. Also, don't forget to sign up for Premier's [Cardiovascular Newsletter](#) to receive e-mail updates about cardiology contracts, industry news, and more.



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New pacemaker gives doctors instant report on heart

11/23/2003

By RENEE C. LEE / Associated Press

Some doctors say a heart-monitoring device that faxes information directly to a physician's office from anywhere in the world can save lives, but federal regulators say it could pose a danger to patients.

The Federal Communications Commission earlier this year banned the device known as a portable messenger, because of fears it could further clog airwaves already crowded with transmissions from high-tech medical gadgets.

The German-based manufacturer, Biotronik, appealed the ruling and expects a decision by the end of the year. The FCC allowed the 3,000 patients who already had the portable messenger to continue using it.

The ruling offers a glimpse of regulation complications and corporate competitions on the horizon as technology factors more into medicine. Meanwhile, patients may lose out on devices that could help them, some doctors say.

"This information has potentially life-saving consequences. Why should we be denied access to this information?" Dr. Allistar Fyfe, a cardiologist at Medical City Dallas Hospital, said of the portable messenger. He has about a dozen patients using the device.

Approved by the FDA in April 2002, the portable messenger uses technology similar to a cell phone and works along with a special pacemaker. The pacemaker sends signals to the portable messenger, which is worn like a pager on a waistband or belt. The device then transmits patient information to doctors.

Doctors can program the device to monitor specific heart activity and to send reports periodically. Patients can also trigger transmission, if they feel something is wrong.

Biotronik said the device costs about \$8,000, and the pacemaker takes about 30 minutes to implant under the collarbone. The device

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- Internships

works as long as it is within 6 feet of the pacemaker, company spokesman Fred Koury said.

The system proved to be a lifesaver for Billie Jo Slade, 71, a retired teacher's assistant from Athens, Texas, diagnosed with a rapid heartbeat.

Two months after installation of her pacemaker in February, the messenger sent reports to her doctor showing that her heartbeats jumped from 70 to 140 a minute. The abnormal rhythms could have led to a stroke if gone undetected.

"My biggest fear was having a stroke," Slade said. "It changed my outlook on doing things."

Slade illustrates how far pacemakers have come. About 10 years ago, pacemakers could only detect malfunctions within the device itself, such as low batteries or connection failure.

"With this device, we can communicate in real time," said Fyfe, Slade's doctor. "We can find out tomorrow night or the next day or in three minutes ... if there's been a change in heart rhythm."

Despite praise from doctors, a competitor of Biotronik that makes a similar device, Minneapolis-based Medtronic, claimed the device's signals do not follow federal rules. It was Medtronic's May 2001 complaint, filed after Biotronik received approval for its device, that led to the FCC ruling in February.

In 2000, the FCC created wireless medical telemetry — a precise block of frequency bands for medical devices — to prevent transmission interference. Devices must make sure they're on an open band before transmitting. Biotronik's device does not do that, the FCC said.

There's also a question of whether the device's transmission meet the FCC's definition of a medical implant event, a technical term for medical emergencies that trigger a transmission. Federal rules say there must be a change in the patient's medical condition that requires a medical response when an implanted device transmits medical information.

"To send a report when there is no change doesn't meet the rules," said Jeff Tobias, an FCC adviser. "If you're going to send a report, there has to be a change in the patient's condition."

Biotronik said its device "squarely fits within the definition of a medical implant event," and that's one of the reasons it appealed the FCC decision.

Medtronic's system is Internet-based. It transmits patient information to a secure server and a doctor can retrieve it from a Web site, company spokeswoman Valerie Lind said.

Both devices are important advances in medicine, said Dr. Stephen Hammill, a cardiologist at the Mayo Clinic in Rochester, Minn., and a member of the North American Society of Pacing and Electrophysiology Heart Rhythm Society.

"If you look five years from now all pacemaker companies will have similar systems," Hammill said.

With 62 million Americans diagnosed with heart disease, pacemakers are a high-stakes industry, generating about \$5 billion a year among the four manufacturers operating in the United States.

Industry analyst John Putnam, with Belmont Harbor Capital-Soleil in Chicago, said it's not unusual to see companies file lawsuits or petitions to delay a competitor's product.

But Lind said that was not Medtronic's intent when it filed its petition.

"We are not trying to limit Biotronik in any way," she said. "We want to ensure the bands designed by the FCC are protected so that patients aren't at risk."

On the Net:

Biotronik: www.biotronik.com

Medtronic: www.medtronic.com

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Telemedicine rings off the hook



Heart implant alerts your doctor when trouble strikes

Cardiologist Dr. Roy Saurberman, notified by fax that 86-year-old Ken Hall had suffered a heart episode, talks to him during an unscheduled office visit. The fax was sent by a cardiac defibrillator implanted in Hall's chest.

Free Windows Media Player **PLAY VIDEO**

By Hampton Pearson
and Steve Lewis
CNBC

NEWARK, N.J., Nov. 7 — A new medical technology called “telemedicine” is taking off. The AARP reports that a baby boomer becomes a senior citizen every 7.5 seconds. And that aging population is embracing technology and taking a more active role in their own healthcare. The demand is fueling a race to deploy thousands of new devices each year, some of which could save some of 500,000 Americans who die each year from sudden cardiac arrest.

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Hampton Pearson
CNBC CORRESPONDENT

LESS THAN SIX months after 86-year-old Ken Hall got a Biotronik cardiac defibrillator implant, it saved his life. The retired Newark, N.J. sanitation worker never felt a thing. But his doctor got a wireless "wake up call."

Cardiologist Dr. Roy Saurberman, notified by fax that his patient had suffered a heart episode, called Hall in for an unscheduled office visit, where he told him for the first time what had happened.

"You had what we call ventricular tachycardia, a potentially life-threatening heart rhythm disturbance," he said. "The good news is the defibrillator's working, you've got a guardian angel over you. Your life is protected, and you're going to do very well."

"Thank you," said Hall. "Thank you, doctor, wonderful."

A \$5 BILLION MARKET

The grandfather of Hall's implant, the first cardiac defibrillator, was patented in 1962. Those paddles became a familiar sight in American homes after countless cameos in TV medical shows and films.

Everything changed in 1980 when Dr. Levi Watkins Johns Hopkins implanted the first defibrillator, which was about the size of a cookie. Since then, more than 300,000 patients have received implantable cardiac defibrillators, also known as ICDs.

The device costs, on average, About \$44,000 and last year made up a \$5 billion market.

Now, in the new millennium, ICDs are speaking out, becoming 24/7 security guards for their owners.

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The moment a Biotronik device detects irregular heart activity, it alerts the physician via fax. For Ken Hall and his family, the technology is simply a miracle.

“I feel a lot of insurance, because without this miracle I think sometimes it’s impossible to use the knowledge that God gives us,” he said.

Medical device giants Guidant and Medtronic are developing similar products. Medtronic is testing an implant in some 20,000 Veterans Administration patients. The Medtronic device uses the Internet, but isn’t automatic. The onus is still on the patient, who through a self-scanning process must deliver updates to their doctor.

But Sauberman believes the open window the Biotronik device offers is wireless nirvana.

“It’s been great,” he said. “Great in terms of us as physicians, nurses, medical care givers to be able to feel that we’re always watching, we’re always listening.”

ROUND-THE-CLOCK SUPPORT

With real-time patient information a reality, the monitoring business is ready to explode. So look for Biotronik to hook up with the likes of Raytel Cardiac Services. Raytel is to your implant what the monitoring company is to your home alarm system. They already provide round-the-clock support for 12,000 cardiologists and 170,000 cardiac patients nationwide.

“There’s an increasing number of patients with implantable devices,” said Dr. Joseph Sappington, Raytel’s medical director. “And it frees us from having the patient come to the office every month. We can virtually make house calls over the telephone.”

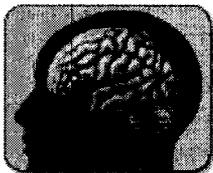
For the millions of Americans living out their golden years up and down the Florida coast, telemedicine breakthroughs can bring the hospital closer to home.

So when the American Telemedicine Association hosted a fall forum at a posh South Florida resort, remote monitoring and home health solutions were center stage. Attendance nearly doubled expectations.

“The types of applications that are available have become more refined,” said John Linkous, the association’s director. “Clinical trials are over. The early studies of the efficacy of telemedicine — how well it works — have been proven.”

But for all its promise, medical technology is on

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a collision course with regulators. Industry advocates complain the FDA approval process is too slow and that Medicare adds to the drag, all of which is making for a highly unpredictable environment for investors and product developers. FDA Commissioner Mark McClellan says he hopes to jump start the process through a series of new initiatives.

“One is a new user fee program where the manufacturers of new devices will pay fees to us to review them,” he said. “That is additional resources that we can use to save time and save effort in getting products to patients.”

McClellan says private insurers, Medicare and his agency must have a meeting of the minds. And companies will have to share trade secrets with more than one regulator in order to get their products to market faster — if so many more people like Ken Hall are destined to have “technology guardian angels” monitoring every heartbeat.

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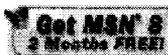
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CARDIO REPORT

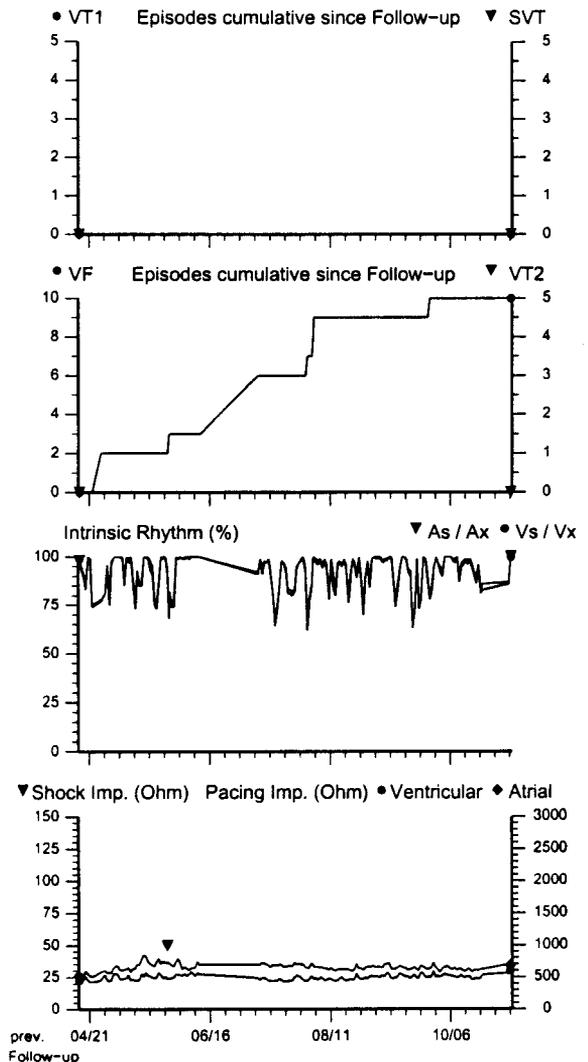
Hotline Tel.: 800-284-6689
Fax: 888-387-2681

To attending physician	Dr. Scott Hessen Fax: 0016108764308
------------------------	--

Patient ID 70124	Patient Device No. SN US200869	Last Message received at Patient Device	11-03-2003 at 08:23:39
	Implant / Serial No. Belos DR-T / 79640124	Last Message received at Service Center	11-03-2003 at 08:23:09
		Consecutive Report No.	16
		Consecutive Report: Date / Time	11-04-2003 at 06:12:48
		Date of Preceding Cardio Report	10-07-2003 at 05:54:39

PERIODIC REPORT

	Since last Follow Up 04-16-2003	Since Implantation
DETECTION		
Episodes in VT1 Zone	0	0
Episodes in VT2 Zone	0	0
Episodes in VF Zone	10	15
SVT	0	0
THERAPY		
ATPs started	0	0
ATPs successful	0	
Shocks started	11	16
Shocks successful	1	
Shocks aborted	10	11
30 J Shock without Success	0	
INTRINSIC RHYTHM* *Detection also during SVT		
	Since restart statistics	Since last Reporting Interval
Atrial senses (As/Ax) [%]	91	90
Ventricular senses (Vs/Vx) [%]	92	92
BATTERY		
Status	BOL 77 %	
Voltage measured on	6.21 V	11-03-2003
LEADS		
	Atrial	Ventricular
Pace Impedance measured on	681 Ohm 11-03-2003	597 Ohm 11-03-2003
Shock Impedance measured on		50 Ohm 05-27-2003
DEVICE STATUS SUMMARY / REMARK		
Status	OK	
Remark		



Monitoring Mode Settings	Monitoring Interval (periodic message from implant):	24 hours
	Reporting Interval between Follow Up (interval of periodic reports):	4 weeks

CARDIO REPORT

To attending physician **Dr. Joseph A. Meacham**
Fax: 0012143204968

Patient ID 41105	Patient Device No. SN US201103	Last Message received at Patient Device	07-08-2003 at 17:40:10
	Implant / Serial No. Philos DR-T / 75171105	Last Message received at Service Center	07-08-2003 at 17:40:17
		Consecutive Report No.	299
		Consecutive Report: Date / Time	07-08-2003 at 17:40:43
		Date of Preceding Cardio Report	07-08-2003 at 15:23:41

Event Report – Ventricular Run (4...8 consecutive VES)

Total Reporting Interval:	Elapsed Monitoring Interval ¹⁾	Since 06-10-2003
		Mean Values * Max Value

Heart Rate			
Mean Ventr. Heart Rate	[bpm]	80	77

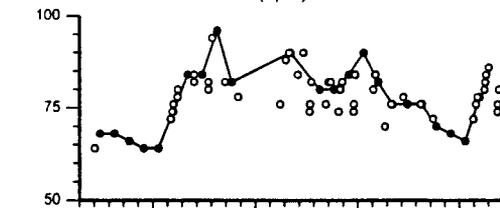
Atrial Rhythm			
Intrinsic Rhythm (As / Ax)	[%]	100	73
No. of Mode Switches		>=52	27 / 24h
Duration of Mode Switches	[%]	100	44

Ventricular Rhythm			
Intrinsic Rhythm (Vs/Vx)	[%]	87	38
Ventricular Rate at Mode Switch	[bpm]	<120	<120 *
No. of Ven. Runs (4...8 consec. VES)		3	>=7 *
No. of Ven. Episodes (>8 consec. VES)		0	>=3 *
Duration of longest Ven. Episode	[min]	<0.5	>=2 *

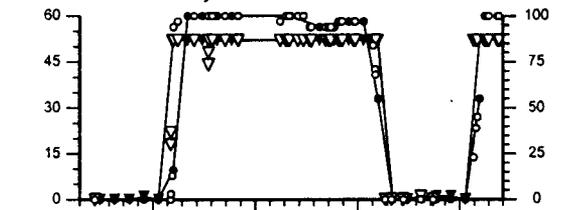
AV Conduction			
AV Synchrony (AxVx/Vx)	[%]	90	92
With Intrinsic Rhythm (AsVs)	[%]	84	35
With Atrial Stimulation (ApVs)	[%]	0	0
With Ventricular Stimulation (AsVp)	[%]	16	36
With Dual Chamber Stimulation (ApVp)	[%]	0	29

System Status	
Atrial Lead Check	OK
Ventricular Lead Check	OK
Mean P-Wave Ampl./prog. Sensitivity	>= 100 % safety margin
Mean R-Wave Ampl./prog. Sensitivity	>= 100 % safety margin
Battery Status	OK

Mean Ventricular Heart Rate (bpm)



Mode Switch./Day and Mode Switch. Duration (%)



Intrinsic Rhythm (%)



AV-Conduction (%)



periodic (circles) event/patient activated (triangles)

Monitoring Mode Settings	¹⁾ Monitoring Interval (periodic Message from implant):	24 hours
	²⁾ Reporting Interval to attending physician:	1 month