

LAW OFFICES
GOLDBERG, GODLES, WIENER & WRIGHT
1229 NINETEENTH STREET, N.W.
WASHINGTON, D.C. 20036

HENRY GOLDBERG
JOSEPH A. GODLES
JONATHAN L. WIENER
MICHAEL A. MCCOIN
BRITA D. STRANDBERG
CHRISTOPHER G. TYGH*

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

*NOT ADMITTED IN D.C.

(202) 429-4900
TELECOPIER:
(202) 429-4912
general@g2w2.com

March 10, 2004

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 counsel to Biotronik, Inc., provided Bruce Romano and Julius Knapp of the Office of Engineering and Technology copies of two press stories concerning the Commission's recent Order issued in the above-referenced proceeding. Copies of both news articles are attached hereto.

Please direct questions concerning this matter to the undersigned.

Respectfully submitted,



Henry Goldberg
Attorney for Biotronik, Inc.

cc: Mr. Julius Knapp (by e-mail)
Mr. Bruce Romano (by e-mail)

FCC ruling allows use of heart-monitoring device

**By RENEE C. LEE Associated Press Writer
March 5, 2004**

DALLAS- A ban on a heart-monitoring device that faxes information directly from the patient to a physician's office has been lifted by federal regulators, striking down a claim that the device poses a risk to patients.

The Federal Communications Commission made the decision Feb. 26 but announced it Friday on its Web site. The ruling allows doctors to resume using the device and allows the German-based manufacturer, Biotronik, to put it back on the market.

"We are ecstatic as a company to be back in business," said Mark Johnson, director of U.S. marketing for Biotronik. "We have several thousand doctors waiting to use the device."

The device, known as a 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 say the device can save lives because it gives them critical information about changes in heart activity in real time, allowing them treat patients right away.

The FCC approved the device in April 2002, but banned it almost a year later after a competing company filed a complaint saying the Biotronik device could interfere with transmissions from other medical devices that share the same airwaves, possibly preventing a patient from quickly receiving treatment. Biotronik appealed the decision.

Federal regulators spent more than a year reviewing its rules on transmissions for high-tech medical devices before deciding the complaint filed by Minneapolis-based Medtronic was unfounded.

"After analysis, we found no reason to inhibit the device," said Ed Thomas, chief engineer for the FCC's Office of Engineering and Technology. "We don't think it creates any harm to patients."

Valerie Lind, spokeswoman for Medtronic, said the company is disappointed with the ruling.

"We continue to believe it's important that medical devices companies comply with the MIC (medical implant communication) regulations and we will continue doing so ourselves," Lind said.

In 2001, federal regulators created wireless medical telemetry _ a precise block of frequency bands for medical devices _ to prevent transmission interference.

"We observe that these devices operate extremely infrequently, about one half second a day, such that the possibility that two devices will be operating simultaneously in close proximity is extremely small," the FCC said in its latest ruling.

But federal regulators still maintain that the Biotronik device's transmission do not meet the FCC 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.

After Biotronik explained in its appeal how the device works and why it is important to have the periodic messaging, federal regulators granted the company a three-year waiver as part of its ruling. The waiver allows the company to continue using the portable messenger until federal regulators change or amend its rules regarding transmissions of high-tech medical gadgets.

Dr. Allistar Fife, a cardiologist at Medical City Dallas Hospital, said he is pleased with the ruling. One of his patients who has the device was hospitalized three times because of heart problems that went undetected. Because of the ban, he could not receive periodic reports from her device.

"We're very excited the FCC has agreed to grant the waiver so this device can be explored and developed further," said Fife, who has about 12 patients who use the device. "We can now effectively treat our patients and give patients more freedom."

Biotronik gets OK to market pacemaker

The German firm, with U.S. headquarters in Lake Oswego, says it is ramping up sales

Published 03/10/04 in The Oregonian newspaper

By BOAZ HERZOG

The Federal Communications Commission has granted Biotronik Inc. a waiver to sell a controversial pacemaker in the United States, rejecting complaints from rival Medtronic Inc.

Biotronik, a German medical device maker with its U.S. headquarters in Lake Oswego, received word from the FCC in late February. Biotronik said Tuesday that it is ramping up sales and marketing efforts for its Philos DR-T pacemaker, which monitors a patient's heart rate and automatically sends vital signs to far-away doctors.

The ruling should translate into the sale of 2,000 to 4,000 more of the implantable devices in the nation each year, said Mark Johnson, Biotronik's marketing director. The units sell for \$5,000 to \$8,000 each, he said.

The ruling also gives Biotronik a new front in which to fight for market share with Medtronic, which filed a complaint that led to the FCC halting sales of the Philos DR-T in the first place.

A Medtronic spokeswoman said the Minneapolis-based company is "disappointed" in the ruling and may appeal the decision to a federal appeals circuit court.

The battle between the two companies began soon after Biotronik announced in fall 2001 that its engineers had created the first implanted medical device with remote data-sending capability that had gained U.S. regulatory approval. The pacemaker works by collecting and reporting the pulmonary signs of a patient back to a doctor's office by way of e-mail, fax or cell phone, regardless of a patient's location.

The system is designed to detect, for example, a potentially lethal cardiac arrhythmia, which are precursors to strokes.

The transmitter inside the implant uses a band of the radio spectrum that regulators have set aside for implanted medical devices. Patients with the pacemaker carry a cell phone-like unit that picks up the implant's radio signal and transmits the data to doctors within 90 seconds, Johnson said.

Medtronic, which makes a similar device and commands about half the market for implanted heart devices, complained to the FCC that Biotronik's pacemaker could interfere with transmissions from other medical devices. In February 2003, after Biotronik had sold about 2,000 of the devices, the FCC asked Biotronik to stop distributing the device and to show that it would not interfere with other transmissions.

While that process continued for the past year, the company continued to sell the pacemaker outside the United States, where Biotronik accounts for 90 percent of its sales.

But the ruling was a blow to Biotronik's aim to expand its 5 percent share of the multibillion dollar U.S. market for implanted heart devices.

Biotronik's Johnson described Medtronic's complaint as a "tactic to slow us down." "They're ten times as large and saw us bringing a revolutionary product to market," he said.

Medtronic spokeswoman Valerie Lind said the company opposed Biotronik's device because it's "best for the safety of patients."

But in late February, the FCC concluded that Biotronik's pacemaker is "highly unlikely to cause interference" and that it was "in the public interest" to grant the company a three-year waiver to sell its monitoring system.

"There's been quite a demand" since that decision, Johnson said. The company expects the pacemaker with wireless transmission capabilities to represent about one-fourth of the 10,000 implantable pacemakers it sells this year in the United States.

Medtronic's Lind said the FCC ruling won't impact the company's business but might appeal the ruling so "we can preserve the integrity of data transmitted by patients to clinicians."