

File No. 0257-EX-ST-2005  
Reference Number: 3658

SUPPLEMENT TO APPLICATION FOR EXPERIMENTAL  
SPECIAL TEMPORARY AUTHORITY

DexCom, Inc. herein supplements its above-referenced application for new experimental Special Temporary Authority ("STA") to provide information requested in correspondence on May 19, 2005.

As stated in its initial application, DexCom has been developing a breakthrough implantable blood glucose monitoring system, allowing convenient and low cost control of diabetes up to now not possible. DexCom is in the process of pursuing clinical studies and seeks experimental authorization to use the devices identified in the application at and in home environments around various major medical facilities in the United States. DexCom's system, expected to cost less than \$30 for the short term sensor, represents a low-cost, medically-valuable and efficient alternative to presently-available blood glucose monitoring techniques. Bringing DexCom's blood glucose monitoring devices to market as soon as possible will reap enormous public health benefits.

In its efforts to bring its glucose monitoring devices to the market, DexCom, in addition to seeking permanent FCC equipment authority, is also required to work with the FDA in order to gain certification for its devices. Owing to the significant public health concerns of diabetes, the FDA has already granted DexCom expedited review of its pre-market approval and, in doing so, has stated in its requirements for gaining final certification that DexCom's short term clinical trials must include 100 people per study. For the approvals that DexCom is seeking from the FDA, it will also need to conduct up to five studies, so a total of 500 transmitters at various locations is required to fully implement DexCom's clinical studies.

Given the large number of patients required in each study, DexCom had to engage a sufficient number of medical programs that were willing to commit their physicians and patients to the development of the equipment. Authority to operate is accordingly herein sought by the FCC consistent with the list of facilities identified in DexCom's application, as it seeks to gain additional technical knowledge as to the functionality of its system while satisfying the important additional FDA requirements.

DexCom's devices have the capability of transmitting blood glucose data continuously. The bulk of DexCom's proposed experimental operations would involve patients who use a short-term sensor, which has the glucose sensing

system under the skin, but the electronics are on the outside of the body. In the case of only twenty units will there be the use of a long-term sensor that is implanted in a patient. Both devices use sensors that obtain blood glucose measures, which are then transmitted every five minutes (288 transmissions a day) by wireless RF telemetry to a cell-phone sized receiver that a patient carries with him or her. Patients can, at a push of a button, learn their current blood glucose levels as well as chart their recent blood glucose levels to determine how well they are maintaining constant blood glucose levels.

The frequent transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels by, for example, injecting insulin. Likewise, the large pool of devices requested in the instant STA request are needed to allow the collection of a series of blood glucose measurements and trends with a frequency that heretofore has not been possible. DexCom maintains that authority to permit it to operate up to 500 units at the various medical facilities identified on its application and in the neighboring home environments is warranted in light of the critical technical information this experimentation will provide and with regard to the public health implications of the use of those devices as DexCom prepares them for certification and marketing.