Exhibit #1 510(k) Summary

SEP 30 2011

This 510(k) Summary is prepared per the request of 21 CFR 807.92.

Date of Preparation	25 AUG 2011
Assigned 510(k) #.	K101273
Sponsor	**Contec Medical Systems Co., Ltd** Establishment Registration Number: 3006979678 No. 24, Huanghe West Road, Economic & Technical Development Zone Qinhuangdao, Hebei, 066004, China
Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No.19, Lane 999, Zhongshan Road (S-2), Shanghai, 200030, China
Proposed Device	Dynamic ECG Systems, TLC5000
Classification	Electrocardiograph, ambulatory, with analysis algorithm; MLO; 870.2800; Class II
Intended Use	Dynamic ECG System, TLC5000, is intended to continuously acquire ambulatory ECG data for up to twelve leads. It can record the ECG data for at most twenty four hours. The ECG data obtained will be stored in the recorder first and then download to PC for analysis, reviewing and printing by a trained physician in health facilities.
Device Description	Dynamic ECG System, TLC5000, mainly consists of two parts: a recorder, analysis software and accessories. The recorder is designed to acquire, display and record ECG signals from patient body surface by ECG electrodes. After been amplified, filtered and analyzed, the ECG signals waveforms, as well as the patient information will be displayed and stored in the memory of the recorder. The information stored can be downloaded to PC; the ECG signal then can be analyzed by the analysis software. The analysis results are only used as advisory basis. The accessories contain disposable electrodes, cables, USB connecting line.
Testing	The following tests were performed to evaluate the safety and effectiveness of the proposed devices: ➢ Electrical Safety Test per IEC 60601-1:1988+A1:1991+A2:1995; ➢ EMC Test per IEC 60601-1-2:2001+A1:2004; ➢ Performance Test Report per IEC 60601-2-47:2001; ➢ Biocompatibility Test per ISO 10993 series standards; ➢ Automatic analysis function verification per AAMI EC 57. The test results complied with FDA recognized standards and be evaluated to determine it was acceptable, therefore, safety and effectiveness were demonstrated substantially equivalent (SE) to the predicate device.
Predicate Device	Matrix Holter System, K051730
SE Conclusion	The proposed device, Dynamic ECG System, TLC5000 is substantially equivalent (SE) to the predicate device, Matrix Holter System, K051730.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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c/o Diana Hong
Shanghai Midlink Business Consulting Co., Ltd.
Suite 5D No 19, Lane 999
Zhongshan No.2 Roads
Shanghai, China 200030

SEP 30 2011

Re: K101273
Trade/Device Name: Dynamic ECG Systems, TLC5000
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MLO
Dated: September 15, 2011
Received: September 16, 2011

Dear Ms. Hong:

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 application (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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K101273 1/1

Premarket Notification Section 510(k) Submission
Report SN: SHA020200909111FDA
Indication for Use Statement

Exhibit #1 Idication for Use Statement

510(k) Number: K101273

Device Name: Dynamic ECG System, TLC5000

Indication for Use:

Dynamic ECG System, TLC5000, is intended to continuously acquire ambulatory ECG data for up to twelve leads. It can record the ECG data for at most twenty four hours. The ECG data obtained will be stored in the recorder first and then download to PC for analysis, reviewing and printing by a trained physician in health facilities.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101273