K121542

## 510(k) SUMMARY

**Picis, Inc.'s Weight Based Dose Converter**

AUG 27 2012

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

Picis, Inc.
100 Quannapowitt Parkway
Wakefield, MA 01880
Phone: (781) 557-3034
Facsimile: (781) 557-3118

Contact Person: Karen A. Iorio

Date Prepared: May 24, 2012

**Device Trade Name**

Picis Weight Based Dose Converter

**Common or Usual Name / Classification Name**

Drug Dose Calculator (Product Code: NDC; 21 C.F.R. 868.1890)

**Predicate Devices**

The Rx Files Corp., TRxF Intelligent Dosing System (K011571)

**Intended Use / Indications for Use**

The Picis Weight Based Dose Converter is designed for use by trained clinicians to calculate any individual patient's dose for a given agent based on a weight based determination by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight based dose.

The Picis Weight Based Dose Converter is not a substitute for clinical reasoning. The Picis Weight Based Dose Converter is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program.

**Technological Characteristics**

The Picis Weight Based Dose Converter is a drug dose conversion feature designed for use with an electronic medical record system. The feature allows a user to convert a drug dose in units per body weight to a total dose. For example, the Weight Based Dose Converter provides for a conversion of an agent dose in milligrams per kilogram of body weight to an agent dose in total milligrams according to the patient's weight.

**Performance Data**

Software verification and validation testing activities were conducted to establish the performance, functionality, and reliability of the Picis Weight Based Dose Converter software. The results of the testing confirmed that the Picis Weight Based Dose Converter software performs as intended.

**Substantial Equivalence**

The Picis Weight Based Dose Converter software is substantially equivalent to the identified predicate device listed above. The Weight Based Dose Converter software has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the subject Weight Based Dose Converter software and its predicate device raise no new issues of safety or effectiveness. Thus, the Picis Weight Based Dose Converter software is substantially equivalent.

**Predicate Device Comparison Table**

| | **Weight Based Dose Converter** | **Predicate TRxF Intelligent Dosing System (K011571)** |
|---|---|---|
| **Intended Use/ Indications for Use** | The Picis Weight Based Dose Converter is designed for use by trained clinicians to calculate any individual patient's dose for a given agent based on a weight based determination by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight based dose. The Picis Weight Based Dose Converter is not a substitute for clinical reasoning. The Picis Weight Based Dose Converter is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program. | The Intelligent Dosing System ("IDS") is a three-part software suite comprised of DoseRx™, InterchangeRx™ and PracticePrescribeRx™. The DoseRx™ is designed for use by trained clinicians to calculate any individual patient's optimal next dose for any given agent. The InterchangeRx™ is designed to switch a patient from one brand of agent to another while maintaining the therapeutic effect of the original agent. The PracticePrescribeRx™ is a dosing simulator that offers graded prescriber training of the next dose calculation scenarios with scalable patient response and surrogate marker inputs that allows the healthcare provider to gain guided and measured experience in calculating the next dose for a new or infrequently used drug. The Intelligent Dosing System is not a substitute for clinical reasoning. The IDS is an aid for trained clinicians based upon significant and properly entered data. Final drug dose recommendations for a patient must be made only after careful consideration of the fully clinical |

| | Weight Based Dose Converter | Predicate<br>TRxF Intelligent Dosing System<br>(K011571) |
|---|---|---|
| | | status of the patient. No medical decision should be based solely upon the results provided by this software program. |
| **Target Population** | In-hospital patients | In-hospital patients |
| **User Population** | Trained healthcare professionals | Trained healthcare professionals |
| **User Input** | Patient weight, numerical dose and unit, agent form and route of administration | Patient's last agent dose, surrogate marker response information, the current dose and the desired surrogate marker response |
| **Dose computation** | Software-based application used to compute total drug dose | Software-based application used to compute next optimal drug dose |
| **Algorithms** | Uses simple mathematical equation to calculate dosing based on patient weight and numerical dose and units | Uses mathematical clinical algorithm to give proposal for dosing based on scalable patient response and surrogate marker inputs |
| **Testing** | Software validation and verification | Software validation and verification |

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

Picis Incorporated
C/O Ms. Janice Hogan
Hogan Lovells US, Limited Liability Partnership
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

AUG 27 2012

Re: K121542
Trade/Device Name: Picis Weight Based Dose Converter
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: August 8, 2012
Received: August 8, 2012

Dear Ms. Hogan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K121542

Device Name: Picis Weight Based Dose Converter

Indications for Use:

The Picis Weight Based Dose Converter is designed for use by trained clinicians to calculate any individual patient's dose for a given agent based on a weight based dose determined by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight based dose.

The Picis Weight Based Dose Converter is not a substitute for clinical reasoning. The Picis Weight Based Dose Converter is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K121542

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