OCT 2 2 2002

EXHIBIT 2

510(k) Summary of Safety and Effectiveness

K022667

HEALTH CARE MFG., INC.
2146 EAST PYTHIAN ST.
SPRINGFIELD, MO 65802
Phone: 417-864-6511
Fax: 417-864-7394

August 9, 2002
Contact: Katrina Moulder, Official Correspondent

1. **Identification of the Device:**
   Proprietary-Trade Name: "HCMI X-Ray" High Frequency Radiographic System
   Classification Name: Stationary X-Ray System, Product Code 90 KPR
   Common/Usual Name: Stationary X-Ray System

2. **Equivalent legally marketed devices** This product is similar in function to the Bennett X-Ray Radiographic System K952672

3. **Indications for Use (intended use)** : "HCMI X-Ray" High Frequency Radiographic System is intended for use by a qualified/trained doctor or technician or both to perform general purpose radiographic examinations of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing or lying in the prone or supine position

4. **Description of the Device:** The "HCMI X-Ray" is a radiographic high frequency stationary x-ray unit which operates from 120/220 V 50-60~ AC.
   HCMI X-Ray Systems available: They are always sold with a radiographic table, either elevating or non-elevating. A wall stand with bucky is optional.
   The FST-10 tubestand is supplied.

   HCMI 100 kHz Generators with Anatomical Programming

Model	mA Range	kVp Range	Max KW
HF-300	25-300	40-125	30
HF-600	25-600	40-125	37.5
HF-3SE	25-300	40-125	30
HF-3SEE	25-300	40-125	30

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart,** "HCMI X-Ray" High Frequency Radiographic System

Characteristic	Bennett X-Ray Radiographic System K952672	"HCMI X-Ray" High Frequency Radiographic System
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	SAME
Performance Standard	21 CFR 1020.30	SAME
Electrical safety	Electrical Safety per Underwriters Laboratories Standard UL-2601(IEC-60601) and IEC 60601, Underwriters Laboratories Standard UL187: UL Standard for Safety for X-Ray Equipment,	SAME,

7. **Conclusion**

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Health Care Manufacturing, Inc. that the "HCMI X-Ray" High Frequency Radiographic System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2002

Health Care MFG., Inc.
% Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015 USA

Re: K022667
Trade/Device Name: "HCMI X-Ray" High Frequency Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: 90 KPR
Dated: August 9, 2002
Received: August 12, 2002

Dear Mr. Kamm:

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); 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K022667

Device Name: "HCMI X-Ray" High Frequency Radiographic System

Indications for Use: "HCMI X-Ray" High Frequency Radiographic System is intended for use by a qualified/trained doctor or technician or both to perform general purpose radiographic examinations of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing or lying in the prone or supine position.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022667