

MAY 03 2002

K 021245  
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**510K Summary Statement for the de Gotzen "synchro"  
Intraoral Dental X-Ray System.**

**General Information**

**Manufacturer:** de Gotzen S.r.l  
Via Roma 45  
21057 OLIGIATE OLONA (Varese ) Italy

Establishment Registration:  
Telephone: (011) 39 0331 376760  
Fax Line: (011) 39 0331 376763  
Contact Person: Antonella GASPARRI, International Compliance Office

**Submitter:** The Gotzen Group, Inc., (dba) TG Group, Inc. Canada  
3505 Laird Road, Unit #7  
Mississauga, Ontario L5L 5Y7

Establishment Registration: #9615032 & Health Canada Establishment: # 692  
Telephone: (877) 557-4888 (Watts Line)  
Fax Line: (905) 820-3215  
Contact Person: Wayne Lebeau, President

**USA Office:** TG Group USA, LLC  
30 Alden Terrace  
Flanders, NJ 07836

Telephone: (973) 927-3730  
Fax Line: (973) 927-4006  
Contact Person: Donald R. Hill, VP Sales & Marketing  
USA FDA Liaison

**Summary Preparation Date:** January 24, 2002

**Name and Classification**

**Device Name:** de Gotzen **synchro**  
Intraoral Dental X-Ray System

**Primary Classification Name:** 90EHD – Unit, X-Ray, Extraoral with Timer

**Classification Panel:** Dental

**Predicate Devices**

The de Gotzen **synchro** Intraoral Dental x-ray System is substantially equivalent to the following previously cleared and currently marketed devices.

Aztech 70  
Gendex Gx770  
Sirona Heliodont Vario  
Dent-x image X-70 Plus  
Belmont Belray 096

**Product Description**

The de Gotzen **synchro** Intraoral Dental X-Ray System is comprised of the following main components:

- X-Ray tubehead and yoke
- Articulating arm
- Horizontal arm, standard length
- Wall Mount
- Electronic control timer (which may be mounted remotely)
- 8" and 12" Collimating cones

Optional components:

- Horizontal arm, short length
- Horizontal arm, long length
- Rectangular collimating cone

The power supply (Timer) is regulated to provide a fixed 70kVp, and the x-ray target current is fixed at 8ma. Predefined exposure times may be selected directly through the control timer switchpads. The range of exposure time is 0.08 through 3.2 seconds

**Intended Use:**

The de Gotzen **synchro** Intraoral Dental X-Ray System is an Extraoral source of x-rays for Intraoral images in dental radiography.

**Comparison of Technological Characteristics:**

Rationale for Substantial Equivalence.

The de Gotzen **synchro** Intraoral Dental X-Ray System shares the same indications for use, similar materials, design, operational, and functional features and therefore is Substantially Equivalent to the predicate devices listed in this summary.

Table comparing performance of de Gotzen synchro with predicate devices:

Specifications	Aztech 70	Gendex Gx770	Sirona Heliodent Vario	Dent-x Image x-70 Plus	Belmont Belray 096	de Goetzen synchro
Registration Number	K984524	K935046	K000672	K000551	K963699	
Line Requirements	110V-120V 50Hz - 60Hz	110V - 130V 60Hz	100V/110V/120V, 11A 220V/230V/240V, 6A 50Hz/60Hz	110V/220V, 50Hz/60Hz	108V - 132V 50Hz/60Hz	220V/230V/240V, 8A 110V - 120V 5.5A 50Hz - 60Hz
Generator Type	AC	AC	AC Single Pulse	AC	AC	AC
Tube Voltage	65 kV	70 kV	70 kV	70 kV	70 kV	70 kV
Tube Current	8 mA	7 mA	7mA	8 mA	10 mA	8 mA
Exposure Time Selection	0.03 -3.0 Sec	3-99 impulses (28 Steps)	0.03 - 3.2 Sec	0.08 -3.2 Sec	0.02 -3.0 Sec	0.08 - 3.2 Sec. 17 Steps
Focal Spot	0.7	0.6mm	0.8mm	0.7 X 0.7 mm	0.8 X 0.8mm	0.7 X 0.7mm
Focal Length	8in/12in	8in/12in	8in/12in	8in/12in	8in/12in	8in/12in
Total Filtration in X-ray tube unit	Unknown	Unknown	>2 mm Al	>2.5 mm Al	>2.1 mm Al	>2.0 mm Al
Leakage Radiation	Unknown	Unknown	0.25 mGy/h (0.25 mA/70kV)	28 mR/hr at 1m from focal spot	Unknown	Less than 2.5 mGy/h
Compatible with Film and Digital	Yes	Yes	Yes	Yes	Yes	Yes

**Conclusion**

The deGotzen synchro Intraoral Dental X-Ray System was found to be /is substantially Equivalent to the predicate devices; the Aztech 70, Gendex Gx770, Siron Heliodont Vario, Dent-x image x-70, and Belmont Belray 096. The de Gotzen **synchro** shares the same indications for use, similar materials, design, operational, and functional features as the current marketed predicate devices. It has been shown to be safe and effective when used as labeled.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 03 2002**

The Gotzen Group, Inc.  
% Mr. Robert Mosenkis  
President  
CITECH  
5200 Butler Pike  
PLYMOUTH MEETING PA 19462-1298

Re: K021245  
Trade/Device Name: deGotzen synchro  
Intraoral X-Ray System  
Regulation Number: 21 CFR 872.1800  
Regulation Name: Extraoral source x-ray system  
Regulatory Class: II  
Product Code: 90 EHD  
Dated: April 18, 2002  
Received: April 19, 2002

Dear Mr. Mosenkis:

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.

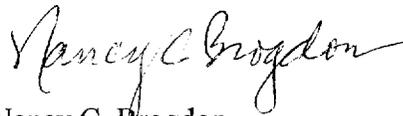
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**XI. INDICATIONS FOR USE STATEMENT**

Applicant: de Gotzen S.r.L.

510(k) Number (if known): k 021245

Device Name: de Gotzen "synchro" Intraoral Dental X-Ray System

Indications for Use: The de Gotzen "synchro" Intraoral Dental X-Ray System is an Extraoral Source X-Ray System, intended to be used for dental radiographic examinations and diagnosis of the teeth, jaw, and oral structures.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Nancy C. Brody  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K021245

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT  
And Radiological Devices

510K Number \_\_\_\_\_