

**510(k) Summary of  
Safety and Effectiveness Data**

OCT 21 1997

**I. General Information**

Device Generic Name: vinyl polysiloxane impression material

Device Trade Name: *Hydroflex - Modified*

Applicant's Name and Address: GC AMERICA INC.  
3737 West 127th Street  
Alsip, IL 60803

**II. Indications**

Hydroflex is intended to be used for taking intra-oral impressions of a person's dentition.

**III. Device Description**

Hydroflex is a dental silicone impression material used for making intra-oral impressions. The resulting impression is poured in dental stone or plaster to form a hard replica of the oral tissues. This product will be available in five viscosities: Regular, Injection, Monophase, Heavy Body and Heavy Body Hard.

**Performance Characteristics**

- ◆ better flow
- ◆ extended working time with snap set
- ◆ dimensional stability
- ◆ improved elasticity and high tear strength

Physical Properties:

<b>Hydroflex Injection</b>	
Total working time (min:sec)	2:45
Setting time (min:sec)	5:00
Consistency (mm)	40
Strain in compression (%)	10.0
Recovery from deformation (%)	99.7
Linear dimensional change (%)	- 0.1
Detail reproduction (mm)	0.020
Compatibility with gypsum (mm)	0.020

<b>Hydroflex Regular</b>	
Total working time (min:sec)	2:00
Setting time (min:sec)	4:00
Consistency (mm)	35
Strain in compression (%)	10.5
Recovery from deformation (%)	99.6
Linear dimensional change (%)	- 0.1
Detail reproduction (mm)	0.020
Compatibility with gypsum (mm)	0.020

<b>Hydroflex Monophase</b>	
Total working time (min:sec)	2:00
Setting time (min:sec)	4:00
Consistency (mm)	36
Strain in compression (%)	2.7
Recovery from deformation (%)	99.7
Linear dimensional change (%)	- 0.1
Detail reproduction (mm)	0.020
Compatibility with gypsum (mm)	0.020

<b>Hydroflex Heavy Body</b>	
Total working time (min:sec)	2:00
Setting time (min:sec)	4:00
Consistency (mm)	32
Strain in compression (%)	2.7
Recovery from deformation (%)	99.7
Linear dimensional change (%)	- 0.1
Detail reproduction (mm)	0.050
Compatibility with gypsum (mm)	0.050

<b>Hydroflex Heavy Body Hard</b>	
Total working time (min:sec)	2:00
Setting time (min:sec)	4:00
Consistency (mm)	32
Strain in compression (%)	2.0
Recovery from deformation (%)	99.0
Linear dimensional change (%)	- 0.1
Detail reproduction (mm)	0.050
Compatibility with gypsum (mm)	0.050

**IV. Equivalence Data**

Marketed Device: Exaflex/Examix (K955932) - GC Corporation, Tokyo, Japan

Test Item (ISO 4823)	Exaflex Injection	Hydroflex Injection
Total working time (min:sec)	2:45	2:45
Setting time (min:sec)	5:00	5:00
Consistency (mm)	40	40
Strain in compression (%)	5.2	10.0
Recovery from deformation (%)	99.6	99.7
Linear dimensional change (%)	- 0.1	- 0.1
Detail reproduction (mm)	0.020	0.020
Compatibility with gypsum (mm)	0.020	0.020

Test Item (ISO 4823)	Exaflex Regular	Hydroflex Regular
Total working time (min:sec)	1:45	2:00
Setting time (min:sec)	4:00	4:00
Consistency (mm)	39	35
Strain in compression (%)	4.5	10.5
Recovery from deformation (%)	99.6	99.6
Linear dimensional change (%)	- 0.1	- 0.1
Detail reproduction (mm)	0.020	0.020
Compatibility with gypsum (mm)	0.020	0.020

Test Item (ISO 4823)	Exaflex Monophase	Hydroflex Monophase
Total working time (min:sec)	1:45	2:00
Setting time (min:sec)	4:00	4:00
Consistency (mm)	35	36
Strain in compression (%)	2.7	2.7
Recovery from deformation (%)	99.7	99.7
Linear dimensional change (%)	- 0.1	- 0.1
Detail reproduction (mm)	0.020	0.020
Compatibility with gypsum (mm)	0.020	0.020

<b>Test Item (ISO 4823)</b>	<b>Examix Heavy body</b>	<b>Hydroflex Heavy Body</b>
Total working time (min:sec)	2:00	2:00
Setting time (min:sec)	4:00	4:00
Consistency (mm)	32	32
Strain in compression (%)	2.5	2.5
Recovery from deformation (%)	99.4	99.7
Linear dimensional change (%)	- 0.1	- 0.1
Detail reproduction (mm)	0.050	0.050
Compatibility with gypsum (mm)	0.050	0.050

<b>Test Item (ISO 4823)</b>	<b>Exaflex Heavy Body</b>	<b>Hydroflex Heavy Body Hard</b>
Total working time (min:sec)	2:00	2:00
Setting time (min:sec)	4:00	4:00
Consistency (mm)	32	32
Strain in compression (%)	2.5	2.0
Recovery from deformation (%)	99.4	99.0
Linear dimensional change (%)	- 0.1	- 0.1
Detail reproduction (mm)	0.050	0.050
Compatibility with gypsum (mm)	0.050	0.050



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. Terry Joritz  
Director-Regulatory Affairs and Quality Control  
GC America Incorporated  
3737 West 127<sup>th</sup> Street  
Chicago, Illinois 60658

OCT 21 1997

Re: K973343  
Trade Name: Hydroflex  
Regulatory Class: II  
Product Code: ELW  
Dated: September, 2 1997  
Received: September 5, 1997

Dear Mr. Joritz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

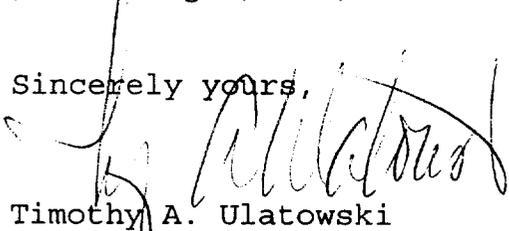
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K973343

ATTACHMENT H

**INDICATIONS FOR USE**

**Device Name:** Hydroflex - Modification

**Indications for use:** Hydroflex is intended to be used for taking intra-oral impressions of a person's dentition

Angela Blackwell for Susan Rimmer  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K973343