

ATTACHMENT "C"

K954867

Date: February 7, 1996

MAI - 8

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS  
For  
510(k) SUBMISSION OF IONOSIT SEAL  
PIT & FISSURE SEALANT

Produced by: Dental Material Gesellschaft (DMG)  
Elbgaustr. 248  
22547 Hamburg  
Germany

Marketed in United States by:

Foremost Dental Mfg. Co., Inc.  
242 South Dean Street  
Englewood, NJ 07631

Contact Person: D. T. Wolf  
242 South Dean Street  
Englewood, NJ 07631  
(201) 894-5500

Predicate Product: Fluoro-Shield  
By: Dentsply  
510(k) #K862284

Product Description: A one-component light cured liquid resin.  
Lightly filled with a fluoride containing glass  
powder.

Intended Use: Ionosit Seal is a dental pit and fissure sealant  
intended to be used to seal the pits and fissures  
of occlusal non-carious posterior teeth.

BASIS OF SUBSTANTIAL EQUIVALENCE:

When tested in standard in-vitro tests for pit and fissure  
sealants, Ionosit seal material demonstrated that in the  
critical areas of adhesion and leakage, it was equivalent to  
Fluoro-Shield. Attached is this reprint from:

Daniel Chan, DMD, MS, DDS,  
The University of Texas Health Science Center  
at San Antonio Dental School  
7703 Floyd Curl Drive  
San Antonio, Texas 78284-7890

Comparison of physical properties:

	<u>Ionosit Seal</u>	<u>Fluoro-Shield</u>
Compressure Strength    mpa	230	270
Tensile Strength    mpa	107	109
Tensile Modulus    mpa	3,000	3.200
Shear Bond Strength    mpa on Etched Enamel, 60 sec. etch	25	22
Change in Volume:		
Immediately	- 0.22%	- 0.22%
After 24 hours	- 0.21%	- 0.21%
After 7 days	+ 0.12%	- 0.07%
Water uptake            (ISO 4049)	50mg/mm <sup>3</sup>	30mg/mm <sup>3</sup>
Water solubility        (ISO 4049)	0mg/mm <sup>3</sup>	0mg/mm <sup>3</sup>

Comparison of chemical composition:

<u>Accepted Typical Formula Pit and Fissure Sealant Component</u>	<u>% by Weight</u>
Bis-GMA	35%
Urethane-dimethacrylate	28%
Hexane-dioldimethacrylate	27%
SiO <sub>2</sub>	9%
Amine-camphor-quinane (as catalyst)	1%

<u>Formula Ionosit Seal Component</u>	<u>% by Weight</u>
Bis-GMA	30%
Glass Powder	28%
TEDMA	25%
Aerosil (fumed silica)	7%
PolyMethacrylated	4%
Oligomaleic acid	2%
Polyacrylic	>1%
Camperquinone/amine (catalyst)	>1%
2,6. Di-tetributyl-hydroxytoluene (stabilizer)	>1%
TiO <sub>2</sub>	>1%