K961455

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510(k) SUMMARY
As Required by 807.92(c)

1. Submitter: DHD Diemolding Healthcare Division
125 Rasbach Street
Canastota, NY 13032

Phone: 315-697-2221
Fax: 315-697-8083

Contact: Jean Wallace, Manager, Regulatory Affairs

2. Device Name
- Trade Name - MedShield
- Common name - Tongue Cover or Guard
- Classification name - Classification - Nebulizer, Direct patient Interface

3. The Micro Spacer and the AeroChamber, designed for use with Metered-Dose Inhalers, are the devices to which we are claiming equivalence.

4. **Device Description**

The MedShield product reduces drug deposition in the tongue when used in conjunction with metered dose inhaler (MDI) medications. The device attaches to an MDI elbow and shields the tongue of the user from the medication spray. Drug that deposits on the device would otherwise be on the users tongue. Based on this, the taste effect of the medications is reduced.

This simple device includes two different features.

1. The patient end of the device covers the tongue. The shape of the patient end may vary to maximize the comfort of a wide range of users.
2. The elbow end of the device includes a universal clip, which attaches the device to all MDI elbows. To satisfy the preferences of various customers, the force required to separate (or attach) the device to various elbows can be modified by adjusting the clip or modifying the taper around the clip.

The MedShield product has been designed to conform with ASTM F963-92, "Standard Consumer Safety Specification on Toy Safety, under Section 4.6, Small Objects, specifically 4.6.2, Mouth-Actuated Toys, and CFR 16-1511.1, "Requirements For Pacifiers", specifically, 1511.5 Structural integrity tests for Small Parts, 1511.5 (d), to ensure that the device does not present a choke hazard.

The MedShield is designed for single patient use. Patients may be given the product for use either in a hospital or home environment for extended time periods. Recommendations for cleaning, in cases of extended time, are included in the instructions for use.

As a prescription item, the labeling of the device contains the required caution statement: "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician."

5. **Intended Use**

The DHD MedShield is a single-patient-use device. The Intended Use of the device is to reduce the taste effect of Metered Dose Inhaler (MDI) drugs by covering the tongue in the taste sensor area.

6. **Technological Information**

6.1 MedShield, Microspacer and Aerochamber are used by attaching to a Metered Dose Inhaler (MDI) elbow, placing part of the device in the mouth and administering the MDI. After activation of the MDI the user inhales the medication while keeping the device in the mouth.

6.2 MedShield attaches to the patient end of the MDI elbow via an integral clip. The patient end of the MedShield masks the area of the tongue that it covers and medication that would have been deposited on that section of the tongue, is deposited on the MedShield.

6.3 Aerochamber attaches to the patient end of the MDI elbow via a flexible thermoplastic opening which surrounds the outer diameter of the elbow patient end. A chamber is affixed to the opening which terminates in a valved mouthpiece at the patient end. After activation of the MDI, large particles impact and deposit within the walls and valving thereby reducing the amount released into the oral cavity of the patient.

6.4 Microspacer attaches to the patient end of the MDI elbow via a conical flexible opening. A small (relative to Aerochamber) chamber is terminated by plastic grating at the patient end. After activation of the MDI, larger particles impact and deposit on the walls and grate reducing the amount released in the oral cavity of the patient.

6.5 **Features and Specifications**

6.5.1 MedShield is one piece and is positioned by on top of the patient's tongue.

6.5.2 Microspacer and Aerochamber have a patient end that serves as mouthpiece. The patient's lips surround the mouthpiece and the patient then inhales through the device.

6.5.3 MedShield is opaque and approximately 1.5 inches by 2.5 inches, rectangular.

6.5.4 Microspacer is opaque and approximately a 1.75 inch long cylinder with a tapered diameter ranging from 1.0 to 0.75 inches. The patient end of the cylinder contains an integral grate.

6.5.5 Aerochamber is opaque at each end and transparent in the center. The device consists of a 4.5 inch long cylinder (1.75 inch inner diameter) with a 1.25 inch x 1.25 inch x 0.75 inch mouthpiece at the patient end and a flexible elliptical opening in which the MDI elbow is inserted.

7. A brief discussion of nonclinical tests conducted on this device and how the results support a determination of substantial equivalent follows:

7.1 Environmental testing was completed to determine the effects of:

Chemical Resistance

The plastic selected for the MedShield is an Acetal resin - Celcon M90. This material has been tested by the manufacturer (Hoeschet Celanese Corp.-Attachment 1) for the effect of various chemicals on physical properties. The three sodium compounds listed are found in dishwasher powders. The Freon, Alcohol and Oleic Acid compounds are found in MDI canisters.

CHEMICAL	RESISTANCE	CHEMICAL	RESISTANCE
Alcohols	Excellent	Freon	Excellent
Ethyl Alcohol	Excellent	Oleic Acid	Good
Methyl Alcohol	Excellent	Sodium Sulfate	Excellent
Propyl Alcohol	Excellent	Sodium Carbonate	Good
		Trisodium Phosphate	Excellent

Cleaning Test: MedShield units were soaked for 5 days in alcohol, dishwashing liquid and vinegar with no physical or cosmetic degradation noted. Units were subjected to 5 cycles of a standard dishwasher with no physical or cosmetic degradation noted. These are considered to be typical cleaning agents/conditions available to users.

Drop Test: MedShield units were dropped 10 times from a height of 1 meter onto a tile covered cement floor without breakage.

7.2 **Comparative Performance Testing**: In each instance tested, the medication deposited on the MedShield was less than that with other devices. Both other devices are cylindrical providing significantly more surface area to collect medication. The lower values for MedShield indicate that only medication that would be deposited on the tongue is affected.

Based on the foregoing information, DHD believes the MedShield performs substantially equivalent to the predicate device(s) and in the opinion of DHD it is substantially equivalent to the predicate device(s) and does not adversely affect safety and effectiveness compared to the predicate device.

CHEMICAL RESISTANCE

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CHEMICAL	RESISTANCE	CHEMICAL	RESISTANCE
Alcohols	Excellent	Freon	Excellent
Ethyl Alcohol	Excellent	Oleic Acid	Good
Methyl Alcohol	Excellent	Sodium Sulfate	Excellent
Propyl Alcohol	Excellent	Sodium Carbonate	Good
		Trisodium Phosphate	Excellent

CLEANING/DROP TESTING

Test Procedure per Sample Request # 432-96-2

CLEANING:

MedShield units were soaked for 5 days in alcohol, dishwashing liquid and vinegar with no physical or cosmetic degradation noted. Units were subjected to 5 cycles of a standard dishwasher with no physical or cosmetic degradation noted. These are considered to be typical cleaning agents/conditions available to users.

DROP:

MedShield units were dropped 10 times from a height of 1 meter onto a tile covered cement floor without breakage.

Attachment No. 1
Chemical Resistance of "Celcon" published by Hoeschet Celanese Corporation

TABLE I

CHEMICAL RESISTANCE OF "CELCON" ACETAL COPOLYMER RESIN

CODE: - - E-Excellent, G-Good, F-Fair, NG-No Good

CHEMICAL	SUITABILITY FOR USE WITH "CELCON"	
	72°F	140°
Acetaldehyde	E	G
Acetic Acid - 20%	F	NG
Acetic Acid - 80%	NG	NG
Acetic Anhydride	G	NG
Acetone	G	G
Adipic Acid	G	F
Alcohols	E	E
Alcohol-Amyl	E	E
Alcohol-Butyl	E	E
Aliphatic Hydrocarbons	E	E
Aluminum Chloride	F	NG
Aluminum Fluoride	F	F
Aluminum Hydroxide	G	F
Aluminum Oxychloride	NG	NG
Aluminum Nitrate	F	NG
Aluminum Sulfate	F	NG
Alums	G	F
Ammonia Gas-Dry	E	E
Ammonia Liquid	E	E
Ammonium Bifluoride	NG	NG
Ammonium Chloride	G	F
Ammonium Carbonate	E	E
Ammonium Fluoride 25%	G	F
Ammonium Hydroxide (all concentrations)	E	E
Ammonium Metaphosphate	E	E

Attachment No. 1

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CHEMICAL	72°F	14(
Ammonium Thiocyanate	G	
Ammonium Nitrate	G	
Ammonium Phosphate	G	
Ammonium Sulfate	G	
Ammonium Persulfate	G	
Amyl Acetate	E	
Amyl Chloride	E	
Aniline	G	
Anthraquinone	E	
Anthraquinonesulfonic Acid	NG	
Antimony Trichloride	NG	
Aqua Regia (Dilute)	NG	
Aqua Regia (Concentrated)	NG	
Aromatic Hydrocarbons	E	
Arsenic Acid	NG	
Barium Carbonate	E	
Barium Chloride	E	
Barium Hydroxide	E	
Barium Sulfate	E	
Barium Sulfide	E	
Beer	E	
Beet Sugar Liquors	E	
Benzaldehyde	E	
Benzene or Benzol	E	
Benzoic Acid	G	
Bismuth Carbonate	E	
Bleach, Laundry 15% Active Cl_2	NG	
Borax	E	
Boric Acid	E	
Brine Solutions	E	
Bromine Liquid	NG	
Bromine Water	NG	
Butane	E	
Butadiene	E	
Butyl Acetate	E	
Butyl Alcohol	E	
Butylene	E	
Butyric Acid	F	

CHEMICAL	72°F
Calcium Bisulfite	F
Calcium Carbonate	E
Calcium Chlorate	NG
Calcium Chloride	E
Calcium Hydroxide	E
Calcium Hypochlorite	F
Calcium Nitrate	E
Calcium Sulfate	E
Carbon Dioxide	E
Carbon Dioxide - Dry	E
Carbon Bisulfide	E
Carbon Monoxide	E
Carbon Tetrachloride	E
Carbonic Acid	E
Castor Oil	E
Caustic Soda (all concentrations)	E
Caustic Potash (all concentrations)	E
Cellosolve	E
Chloracetic Acid	NG
Chloral Hydrate	G
Chloric Acid 20%	NG
Chlorine Gas (Dry)	NG
Chlorine Gas (Wet)	NG
Chlorine Water	NG
Chlorobenzene (Mono)	E
Chloroform	E
Chlorosulfonic Acid	NG
Chrome Alum	G
Chromic Acid (all concentrations)	NG
Citric Acid	G
Cocomut Oil	E
Copper Chloride	G
Copper Cyanide	G

CHEMICAL	72°F	1/
Copper Fluoride	G	
Copper Nitrate	E	
Copper Sulfate	E	
Cottonseed Oil	E	
Cresol	F	
Cresylic Acid - 50%	G	
Cyanide Plating Solutions	F	
Cyclohexanone	E	
Disodium Phosphate	G	
Distilled Water	E	
Dextrin	E	
Dextrose	E	
Diazo Salts	F	
Diglycolic Acid	G	
Dimethylamine	NG	
Dioctylphthalate	E	
Ethers	E	
Ethyl Acetate	E	
Ethyl Acrylate	G	
Ethyl Alcohol	E	
Ethyl Chloride	E	
Ethyl Ether	E	
Ethylene Bromide	E	
Ethylene Chlorhydrin	G	
Ethylene Dichloride	E	
Ethylene Glycol	E	
Ethylene Oxide	E	

CHEMICAL	72°F	140
Fatty Acids	G	F
Ferric Chloride	G	F
Ferric Nitrate	G	F
Ferric Sulfate	G	F
Ferrous Chloride	G	F
Ferrous Sulfate	G	F
Fluoborate Salts	G	
Fluobroic Acid	NG	
Fluosilicic Acid and Salts	G	F
Formaldehyde	E	E
Formic Acid	NG	N
Freon	E	E
Fructose	E	E
Fruit Juices, Pulp	E	G
Gallic Acid	G	F
Gasoline - Sour	E	E
Gasoline - Refined	E	E
Glycolic Acid	F	N
Glucose	E	E
Glycerine or Clycerol	E	E
Glycols	E	E
Heptane	E	E
Hexane	E	E
Hydrobromic Acid	NG	N
Hydrochloric Acid (all concentrations)	NG	N
Hydrocyanic Acid - Hydrogen Cyanide	E	G
Hydrofluoric Acid	NG	N
Hydrogen	E	E

CHEMICAL	72°F
Hydrogen Peroxide (Dilute)	NG
Hydrogen Peroxide (Concentrated)	NG
Hydrogen Sulfide - Dry	G
Hydrogen Sulfide - Wet Aqueous Sol.	F
Hydroquinone	E
Hydroxylamine Sulfate	G
Hypochlorous Acid	NG
Iodine and Solutions	NG
Kerosene	E
Lacquer Solvents	E
Lactic Acid	G
Lard Oil	E
Lauric Acid	G
Lauryl Chloride	E
Lead Acetate	E
Linoleic Acid	G
Linseed Oil	E
Liqueurs	E

CHEMICAL	72°F
Magnesium Carbonate	E
Magnesium Chloride	E
Magnesium Hydroxide	E
Magnesium Nitrate	E
Magnesium Sulfate	E
Malic Acid	G
Maleic Acid	G
Mercuric Chloride	E
Mercuric Cyanide	E
Mercurous Nitrate	E
Mercury	E
Methyl Alcohol	E
Methyl Chloride	E
Methyl Ethyl Ketone	G
Methyl Sulfate	G
Methyl Sulfuric Acid	NG
Methylene Chloride	E
Milk	E
Mineral Oils	E
Mixed Acid - 40% Sulfuric, 15% Nitric	NG
Molasses	E
Mineral Spirits	G
Naptha	E
Natural Gas	E
Nickel Chloride	F
Nickel Nitrate	F
Nickel Sulfate	G
Nicotine	G
Nicotinic Acid	G
Nitric Acid - Dilute (under 25%)	NG
Nitric Acid - Conc. (42° Be.)	NG
Nitric Acid - Fuming	NG
Nitrobenzene	E
Nitrogen Oxides	F

CHEMICAL	72°F	140
Oils & Fats	E	E
Oleic Acid	G	E
Oleum	NG	N
Oxalic Acid	F	N
Oxygen	G	N
Ozone	NG	N
Palmitic Acid	G	E
Perchloroethylene	E	E
Petroleum - Crude	E	G
Phenol	F	N
Phenylhydrazine	G	N
Phosgene	NG	N
Phosphoric Acid - Dilute	NG	N
Phosphoric Acid - Medium Conc.	NG	N
Phosphoric Acid - Concentrated	NG	N
Phosphorous Trichloride	NG	N
Photographic Solutions	F	N
Phthalic Acid	G	G
Picric Acid	NG	N
Plating Solutions	F	N
Potassium Bicarbonate	G	G
Potassium Bichromate	NG	N
Potassium Borate	G	G
Potassium Bromate	F	N
Potassium Bromide	E	G
Potassium Carbonate	G	G
Potassium Chloride	E	G
Potassium Cyanide	G	G

CHEMICAL	72°F
Potassium Dichromate	F
Potassium Ferricyanide	F
Potassium Ferrocyanide	F
Potassium Fluoride	E
Potassium Hydroxide (all concentrations)	E
Potassium Iodide	G
Potassium Nitrate	G
Potassium Perborate	F
Potassium Perchlorate	NG
Potassium Permanganate	NG
Potassium Persulfate	NG
Potassium Sulfate	E
Propane	E
Propyl Alcohol	E
Propylene Dichloride	E
Rayon Coagulating Bath	F
Sea Water	E
Selenic Acid	NG
Silicic Acid	E
Silver Cyanide	F
Silver Nitrate	F
Silver Plating Solutions	F
Soap Solutions	E
Sodium Acetate	E
Sodium Benzoate	G

CHEMICAL	72°F	140°
Sodium Bicarbonate	G	F
Sodium Bisulfate	G	F
Sodium Bisulfite	G	F
Sodium Bromide	G	G
Sodium Carbonate	G	G
Sodium Chlorate	G	F
Sodium Chloride	E	E
Sodium Cyanide	F	NC
Sodium Dichromate	F	NC
Sodium Ferricyanide	G	F
Sodium Ferrocyanide	G	F
Sodium Fluoride	E	E
Sodium Hydroxide (all concentrations)	E	E
Sodium Hypochlorite	F	NC
Sodium Nitrate	G	G
Sodium Nitrite	G	F
Sodium Silicate	G	G
Sodium Sulfate	E	E
Sodium Sulfide	E	G
Sodium Sulfite	E	F
Sodium Thiosulfate	G	G
Sour Crude Oil	E	E
Stannic Chloride	G	F
Stannous Chloride	G	F
Stearic Acid	G	F
Sugar Solutions	E	E
Sulfur Dioxide - Dry	E	E
Sulfur Dioxide - Wet	G	F
Sulfuric Acid - Dilute (Under 25%)	NG	NC
Sulfuric Acid - Med. Conc. (25-80%)	NG	NC
Sulfuric Acid - Conc. (over 80%)	NG	NC
Sulfurous Acid	NG	NC
Sulfur Trioxide	NG	NC

CHEMICAL	72°F	140°
Tannic Acid	G	F
Tanning Liquors	G	G
Tartaric Acids	G	F
Tetraethyl Lead	E	G
Thionyl Chloride	F	NR
Tin Salts	G	F
Toluene or Toluol	E	G
Trichloroethylene	E	G
Triethanolamine	E	E
Triethylamine	E	E
Trisodium Phosphate	E	G
Turpentine	E	E
Urea	E	G
Urine	E	G
Vinegar	E	G
Water - Acid Mine Water	E	G
Water - Demineralized	E	E
Water - Fresh	E	E
Water - Salt	E	E
Whiskey	E	E
White Liquor	E	E
Wines	E	E

CHEMICAL	72°F	140°
Xylene or Xylol	E	E
Zinc Chloride	F	F
Zinc Sulfate	F	F