K091200

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AUG 21 2009

4.0 510(k) Summary:

In accordance with 21 CFR Section 807.92, XTRACT Solutions, LLC. Is submitting the following 510(k) Summary:

4.1 Submitter Information –

XTRACT Solutions, LLC.
9495 SW Locust, Suite E
Portland, OR 97233, USA
FDA Registration No.: Pending
Owner / Operator No.: EIN 931264310

4.2 Preparer of Submission and Contact for Information –

Lowrey RA/QA Solutions, Inc.
Keith Lowrey, Managing Director
611 South Schoolhouse Creek Rd.
Grants Pass, OR 97526
Phone: 541-476-1628

4.3 Name of Device –

4.3.1 Trade / Proprietary Name:

XTRACT Syringe Key System.

4.3.2 Common / Usual Name:

Hypodermic Syringe Accessory Spacer or Holder

4.3.3 Classification Name:

Accessory Device to Piston Hypodermic Syringe

4.4.4 Regulation Number:

21 CFR 880.5860

4.4.5 Product Code:

The product code for the Syringe Keys is **FMF**.

4.4.6 Class:

Class II (performance standards).

4.4 Substantial Equivalence –

This submission establishes the substantial equivalence of the ***XTRACT Solutions, LLC., Syringe Keys*** as an accessory to piston hypodermic syringes such as the following predicate device:

4.4.1 Pavel Jordan & Associates, Inc.'s Count-A-Dose, K883311, SE Date: 09/15/1988.

4.5 Description of the Device –

4.5.1 The XTRACT Syringe Key is a hand held passive tool and an accessory designed to conveniently and ergonomically fit between the plunger thumb rest and the finger grip of piston hypodermic syringes.

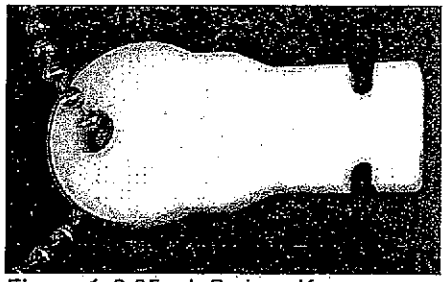

Figure 1 0.05 mL Syringe Key

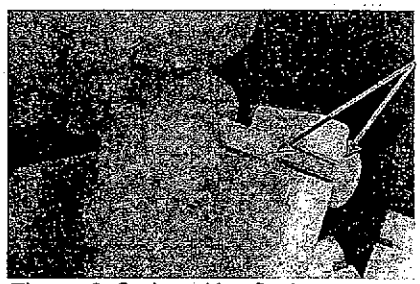

Figure 2 Syringe Key fits between plunger thumb rest and finger grip

4.5.2 Designed to fit the Terumo SurSaver and Greer Optimix (GROM-23) Mixing Syringes, the XTRACT Syringe System facilitates the user in obtaining rapid, accurate and precise volumetric draws from vials containing vaccines, allergenic extracts and medications.

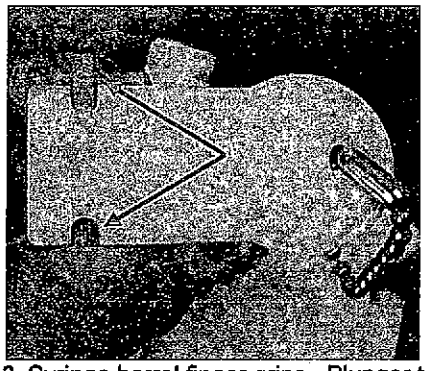

Figure 3 Syringe barrel finger grips Plunger thumb rest

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4.6 Indications for Use –

The *XTRACT Solutions Syringe Keys* are indicated as accessories for specified commercially available piston hypodermic syringes (for medical purposes) and designed to control the distance the syringe plunger can be drawn through the syringe barrel and to facilitate the user in obtaining accurate, consistent and precise volumetric draws from vials containing liquids such as vaccinations, allergenic extracts and medications. The XTRACT Solutions Syringe Keys are designed and should be used only with the Terumo SurSaver Mixing Syringes (product code SS01A2313T) and/or the Greer *Optimix* (GROM-23) SurSaver Mixing Syringes.

4.7 Specifications –

4.7.1 The Syringe Keys are available in sets that are designed and calibrated for the Terumo SurSaver Mixing Syringes (product code SS01A2313T) and/or the Greer *Optimix* (GROM-23) SurSaver Mixing Syringes.

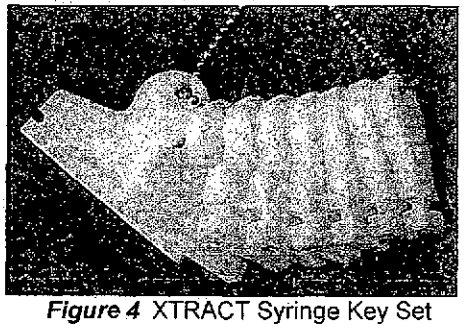


Figure 4 XTRACT Syringe Key Set

4.7.2 The Syringe Key Set contains eight (8) individual Syringe Keys which are attached together by a stainless steel round-bead chain. A set contains keys for the following volumetric draws:

Key Volume:
0.05 mL
0.10 mL
0.15 mL
0.20 mL
0.25 mL
0.30 mL
0.50 mL
1.00 mL

0011

4.7.3 Channels in both surfaces of the Key run along the width from edge to edge. The syringe plunger's thumb rest is inserted at one edge of the channel, the plunger is pulled from the syringe barrel as it is placed in the channel and the finger rest of the syringe barrel is located on the opposite channel edge.

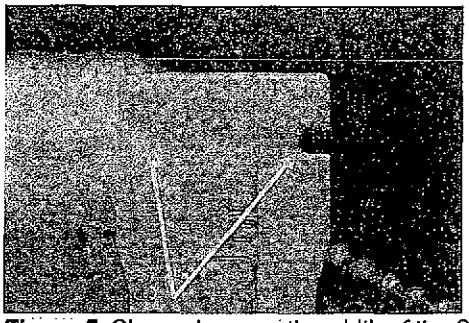


Figure 5 Channel across the width of the Syringe Key.

4.7.4 The XTRACT Solutions Syringe Keys will be sold by prescription only and labeling with bear the statement, ***"Caution: Federal Law restricts this device to sale by or on the order of a physician."***

4.8 Technological Characteristics in Comparison to the Predicates –

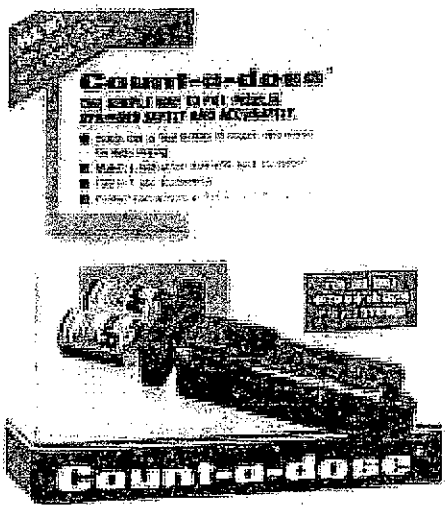
4.8.1 Predicate Device –

The XTRACT Solutions Syringe Key System is substantially equivalent to the Pavel Jordan & Associates, Inc.'s Count-A-Dose, K883311, SE Date: 09/15/1988.

Count-a-Dose Insulin Holder

Description – The simple way to fill insulin syringes safely and accurately.

Manufacturer: MEDICOOL INC



0012 (a)

4.8.2 Materials –

Materials used to fabricate the XTRACT Syringe Keys are polymers that have a long use in medical devices such as white delrin (polyoxymethylene) and polyethylene. The Count-A-Dose 510(k) documentation provides no information about materials used to make the device.

4.8.3 Performance Comparison–

As an ***accessory*** for the hypodermic syringe, the Syringe Keys and the Count-A-Dose are **designed to control** the distance that the syringe plunger can be pulled through the syringe barrel by functioning as a "spacer" fitting on the plunger between the thumb rest and the barrel's finger rest/flange. The devices assist the user in withdrawing precise and accurate liquid volume withdraws from a vial. The devices do not facilitate or assist the user with injecting the contents of the hypodermic syringe.

Figure 6 Plunger thumb rest in channel.

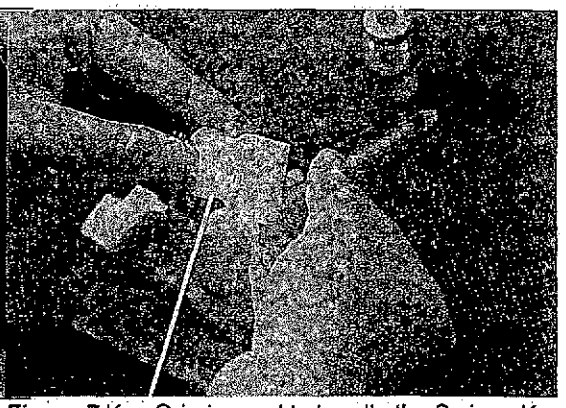


Figure 7 Key Grip is used to handle the Syringe Key.

4.9 Performance Testing –

4.9.1 The Syringe Keys were designed by first establishing an empirical (not just mathematic) relationship of plunger travel to dispensed volume (weight). This data was then used to establish the ideal physical size of the syringe keys (the "Syringe Key Design" worksheet). This process was used with each of the eight (8) volume sizes of each key from the Syringe Key Sets.

4.9.2 Upon receipt of the machined prototypes, a First Article Inspection was performed to verify that all dimensions met drawing specifications and requirements as noted in Table No. 1.

Table No. 1, First Article Report

Draw Volume (mL) vs. Syringe Key Channel Distance (Inches)

Sample	*mL*	*0.1mL*	*0.15mL*	*0.25mL*	*0.5mL*	*1.0mL*
Nominal	inch	***0.7481***	***0.8622***	***1.0905***	***1.6612***	***2.8026***
1		0.7475	0.8630	1.0905	1.6580	2.7970
2		0.7475	0.8615	1.089	1.6605	2.8020
3		0.7470	0.8610	1.090	1.6610	2.8010

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The channel length measurements of the actual syringe keys and the "draw volumes" were evaluated and compared. Using the Syringe Keys, piston hypodermic syringes with needles were introduced into the septums of vials containing H_20.

The liquid was drawn from the vials and dispensed into tarred weighing dishes and subsequently weighed. Weight measurement analyses were conducted on each of the five (5) different Syringe Keys at a minimum of 3 times.

4.9.3 Performance data demonstrates that the Syringe Keys facilitate the user in obtaining more accurate, precise and reproducible volume draws as compared to the standard method or visualization procedure. See Tables No. 2, 3, 4, 5 and 6.

4.9.4 Because the Count-A-Dose device is no longer being manufactured and not available, comparison testing was not possible.

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Table No. 2, Performance Testing – Comparing Multiple Syringe Draws Using the Syringe Keys:

Volumetric testing of the Greer Optimix Syringe (GROM-23)

First Artricle Testing conducted on first articles received from Maxwell Mold (#500) on 06/06/08

		Mass (Grams)					Deviation Validation							
Syringe	Key	0.1mL	0.15mL	0.25mL	0.5mL	1.0mL	Sum	Normalized	0.1mL	0.15mL	0.25mL	0.5mL	1.0 mL	Average
Ideal (g)		0.0997	0.1495	0.2491	0.4983	0.9965	1.9931	39.862	0	0	0	0	0	0
A	1	0.103	0.151	0.249	0.502	0.993	1.998	39.96	0.0033	0.0015	-1E-04	0.0037	-0.0035	0.00165
	2	0.1	0.15	0.25	0.501	1	2.001	40.02	0.0003	0.0005	0.0009	0.0027	0.0035	
	3	0.103	0.149	0.251	0.502	1	2.005	40.1	0.0033	-0.0005	0.0019	0.0037	0.0035	
B	1	0.101	0.154	0.252	0.497	0.992	1.996	39.92	0.0013	0.0045	0.0029	-0.0013	-0.0045	0.00218
	2	0.101	0.151	0.251	0.502	1	2.005	40.1	0.0013	0.0015	0.0019	0.0037	0.0035	
	3	0.104	0.153	0.253	0.501	1	2.011	40.22	0.0043	0.0035	0.0039	0.0027	0.0035	
C	1	0.099	0.151	0.252	0.496	0.995	1.993	39.86	-0.0007	0.0015	0.0029	-0.0023	-0.0015	0.00145
	2	0.1	0.152	0.25	0.5	1.002	2.004	40.08	0.0003	0.0025	0.0009	0.0017	0.0055	
	3	0.102	0.151	0.249	0.5	1.002	2.004	40.08	0.0023	0.0015	-1E-04	0.0017	0.0055	
D	1	0.095	0.144	0.246	0.491	0.99	1.966	39.32	-0.0047	-0.0055	-0.0031	-0.0073	-0.0065	-0.00402
	2	0.094	0.144	0.247	0.497	0.993	1.975	39.5	-0.0057	-0.0055	-0.0021	-0.0013	-0.0035	
	3	0.097	0.148	0.246	0.494	0.993	1.978	39.56	-0.0027	-0.0015	-0.0031	-0.0043	-0.0035	
Average (g)		0.09992	0.14983	0.24967	0.49858	0.99667	Average Deviation (g)		0.00022	0.00033	0.00057	0.00028	0.00017	0.00031
Std. Deviation		0.00318	0.00316	0.00235	0.00358	0.00438	Std. Deviation (g)		0.00318	0.00316	0.00235	0.00358	0.00438	0.00291

Max Deviation (g)	0.00550
Minimum Deviation (g)	-0.00730
Average Deviation (g)	0.00031
Std. Deviation (g)	0.00333

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Table No. 3, Comparison Data – Three Users Hand Filling Two Different Piston Hypodermic Syringes:

	Lynn Miller						Ann McAdams						Brooke Jeppson					
	Syringe A			Syringe B			Syringe A			Syringe B			Syringe A			Syringe B		
	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
0.05 mL	0.06	0.06	0.07	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.07	0.06	0.06	0.06	0.06	0.05	0.06	0.06
0.15 mL	0.16	0.16	0.17	0.17	0.16	0.15	0.16	0.16	0.16	0.16	0.17	0.16	0.16	0.16	0.16	0.15	0.16	0.16
0.20 mL	0.21	0.21	0.21	0.2	0.21	0.21	0.21	0.21	0.21	0.21	0.2	0.21	0.2	0.21	0.2	0.21	0.21	0.2
0.30 mL	0.31	0.3	0.31	0.31	0.31	0.3	0.3	0.3	0.3	0.31	0.31	0.31	0.3	0.3	0.3	0.3	0.3	0.3
0.50 mL	0.51	0.5	0.5	0.5	0.51	0.5	0.48	0.5	0.49	0.51	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.49
1.00 mL	0.99	0.99	0.99	0.99	1	0.99	0.97	0.98	0.98	0.99	0.99	0.99	0.99	0.99	0.99	0.99	0.98	0.99
	grams			grams			grams			grams			grams			grams		

Table No. 4, Data demonstrates User technique in obtaining accurate and reproducible liquid draws by standard method without Syringe Keys.

0015

Visual Dispensation Results - 108 Sample, 3 Subjects, 2 Specimens

Dose	Average	Std. Dev.	Min	Max	Tol. +	Tol. -
0.05	0.061	0.004	0.05	0.07	0.02	0
0.15	0.161	0.005	0.15	0.17	0.02	0
0.2	0.207	0.005	0.2	0.21	0.01	0
0.3	0.304	0.005	0.3	0.31	0.01	0
0.5	0.499	0.007	0.48	0.51	0.01	-0.02
1	0.988	0.006	0.97	1	0	-0.03

Max Deviation (g)	0.02000
Minimum Deviation (g)	-0.03000
Average Deviation (g)	-0.00167
Std. Deviation (g)	0.00548

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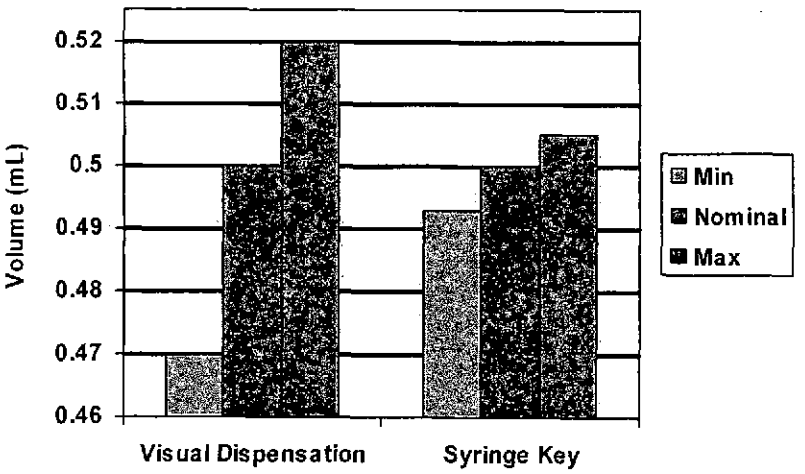
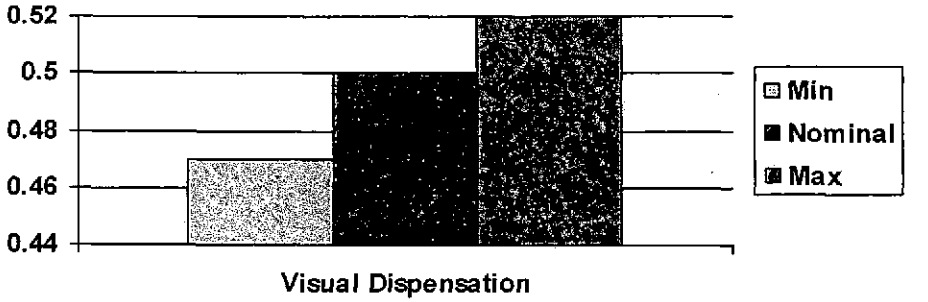
Table No. 5, Comparison of Accuracy and Precision – Visual (standard method) Dispensation vs. Syringe Keys:



Data demonstrates the Syringe Keys provide better accuracy and reproducibility than stand methods.

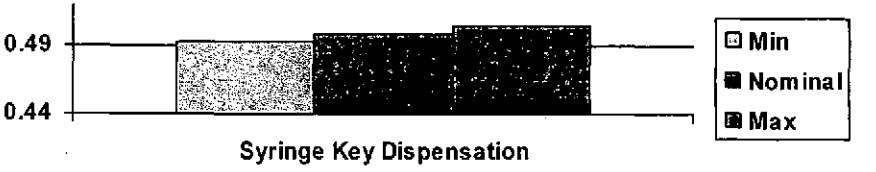
Table No. 6, Visual Dispensation or Standard Method



Data demonstrates visual dispensation or standard method results in a wider range of volume draws than the Syringe Keys.

0016

Table No. 7, Syringe Key Dispensation



Data indicates the Syringe Keys facilitates the user in obtaining a more accurate, precise and consistent draw with the hypodermic syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

XTRACT Solutions, LLC
C/O Mr. Keith Lowrey
Solutions MDI, Incorporated
611 South Schoolhouse Creek Road
Grants Pass, Oregon 97526

AUG 21 2009

Re: K091200
Trade/Device Name: XTRACT Syringe Keys
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 28, 2009
Received: August 12, 2009

Dear Mr. Lowrey:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): To be determined by FDA

Device Name: XTRACT Syringe Keys

Indications for Use:

The *XTRACT Solutions Syringe Keys* are indicated as accessories for specified commercially available piston hypodermic syringes (for medical purposes) and designed to control the distance the syringe plunger can be drawn through the syringe barrel and to facilitate the user in obtaining accurate, consistent and precise volumetric draws from vials containing liquids such as vaccinations, allergenic extracts and medications. The XTRACT Solutions Syringe Keys are designed and should be used only with the Terumo SurSaver Mixing Syringes (product code SS01A2313T) and/or the Greer *Optimix* (GROM-23) SurSaver Mixing Syringes.

Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091200