6-4-02

K013213

510(k) Summary of Safety and Effectiveness Information
Hyperion VisiQuant™ ANA Test Kit
September 25, 2001
Revised: May 31, 2002

Hyperion, Inc.
14100 S.W. 136th Street
Miami, FL. 33186
Contact Person: Radha Goolabsingh at 305-238-3020 x202 or Victor Rana at 305-238-3020 x208, or by facsimile at 305-232-7375.

Trade or Proprietary Name: Hyperion VisiQuant™ ANA Test Kit

Common or Usual Name: ANA IFA Kit

Classification Name: Anti nuclear Antibody immunological test system

Registration Number: *Manufacturer*

Hyperion, Inc. 1028110
14100 S.W. 136th Street
Miami, Florida 33186

The proposed Hyperion VisiQuant™ ANA Test Kit is substantially equivalent to the BION Antinuclear Antibody (ANA) Test Kit/Control manufactured by BION Ent. Ltd., previously cleared under Document Control No., K872845, on 01/17/87. The proposed and the predicate device are *in-vitro* diagnostic products, intended for use to determine the antinuclear antibody in human serum to aid in the diagnosis of certain autoimmune diseases by utilizing the indirect fluorescent antibody technique (IFA).

The proposed Hyperion VisiQuant™ ANA Test Kit differs from the BION Antinuclear Antibody (ANA) Test Kit/Control in the configuration of the individual components included in their respective kits. They also differ in the way the results are read. The BION slides are serially diluted and visually read to determine the titer. The VisiQuant™ ANA slides are read off a standard curve to provide the titer.

VisiQuant™ ANA is a unique ANA IFA. The test samples are assayed with a single dilution as in the traditional qualitative procedure to determine positive/negative and pattern while obtaining a VisiQuant titer from the same image. The stained slides are read objectively with a digital camera through the IFA microscope to measure the fluorescence intensity of reacted substrate (HEp-2 cells). The VisiQuant titer of the test sample is interpolated from a standard curve. VisiQuant ANA uses a unique fluorophore, La Jolla Blue (LJB), which has a longer fluorescence life (photostability) than fluorescein. LJB has near-infrared peak excitation and emission wavelengths to minimize autofluorescence commonly present in biological substances.

The antigen of the ANA substrate is a human epithelial cell (HEp-2) which are cultured and fixed in wells of a glass slide. Diluted test serum samples are placed in the wells and incubated. If ANA are present, they will bind with the antigens expressed by the cells. After washing the wells to remove unbound antigen, the conjugate (La Jolla Blue labeled goat antibody to human IgG) is added and incubated. The conjugate will bind immunologically to the bound ANA on the HEp-2 cell antigens. After another washing of the wells to remove unbound conjugate, the wells are read with a microscope equipped with a digital camera and computer to obtain the immuuunofluorescence image for the determination of the absence (negative) or presence (positive) of ANA pattern(s), as in the commonly used qualitative (screen) procedure for ANA IFA.

For the positive sample, a VisiQuant titer may be obtained by saving the image to a tagged image file format (TIF) file for processing by the VisiQuant software. The software calculates a fluorescence intensity unit (FIU) value. The FIU is calculated by measuring the average brightness of the image from the camera. It then calculates the mean brightness of the picture elements (pixels) in two groups, one above the image average and one below. The difference between the two group mean values is reported as the FIU value. The FIUs and ANA titers of Calibrators assayed in the same run are used to build a standard curve, from which the VisiQuant titer of the test sample is interpolated.

A comparative evaluation of the proposed Hyperion VisiQuant™ ANA Test Kit demonstrated substantial equivalence to the BION Antinuclear Antibody (ANA) Test Kit/Control. The results are shown in the following tables and diagrams:

Table 1. Agreement in Test Results

VisiQuant ANA	No. samples with Bion Test results		
	Negative	Positive	Total
Negative	92	6	98
Positive	1	96	97
Total	93	102	195

Agreement for negative results = 92/93 = 98.92 %
Agreement for positive results = 96/102 = 94.12 %

Table2. Qualitative Results

Negative (Neg); Homogenous (H); Speckled (S); Nucleolar (N); Centromere (C)

VisiQuant pattern	No. test samples with Bion Test pattern								
	Neg	H	S	N	C	H,S	H,N	S,N	Total
Neg	92		5			1			98
H	1	36							37
S			27						27
N				4					4
C					4				4
H,S			2			10			12
H,N				1			9	2	12
S,N								1	1
Total	93	36	34	5	4	11	9	3	195

Pattern agreement for samples positive by both tests = 91/96 = 94.79 %;
for Bion positive samples = 91/102= 89.21 %

Table 3. Discrepant samples (Negative, --; positive, titer with pattern; Speckled (S); Homogenous (H) and Nucleolar (N); positive but not titrated, n.a.). Borderline reactivity accounts for 7 discrepancies as detailed below. Six (6) showed titers of 40 by the Bion ANA but negative by VisiQuant ANA test; one (1) was negative by the Bion ANA but positive low titer of 175 by the VisiQuant ANA test. Slight differences in assay detection and in reading could account for these discrepancies. Some normal subjects may demonstrate low level ANA's which are clinically insignificant.

Item no.	Sample ID	Bion test		VisiQuant ANA	
		Titer	Pattern	Titer	Pattern
1	W-27	--		175	H
2	Y-N17	40	S	--	--
3	Y-N25	40	S	--	--
4	W-21	40	S	--	--
5	W-2	40	S	--	--
6	W-14	40	H,S	--	--
7	Y-SS2	n.a.	S	--	--
8	X-B15	n.a.	S	128	H,S
9	X-B8	160	N	196	H,N
10	W-24	40	S,N	254	H,N
11	W-5	1280N; 160S		227	H,N
12	W-41	640	S	189	H,S

Table 4. Titration of 11 serum samples with VisiQuant ANA. Because VisiQuant titer values could be underestimated for some test samples with centromere, nucleolar or some speckled patterns, nine (9) such samples were titrated by the traditional 2-fold serial dilution and assayed with the VisiQuant ANA. The results as summarized below revealed the equivalence of VisiQuant ANA titers from titration with Bion's IFA ANA titers. Two high positive controls (items 10 and 11) were included in the experiment.

Item no.	Sample ID	VisiQuant ANA			Bion IFA ANA Titer & Pattern
		Assay at 1/40		Titration	
		Pattern	Titer	Titer*	
1	W-5	H, N	227	160H,N	1280N; 160S
2	X-C2	C	215	1280	2560C
3	X-C4	C	135	1280	2560C
4	Z8	C	60	640	640C
5	Z6	N	95	240	640N
6	Z11	N	72	960	640N
7	X-B12	S	104	960	1280S
8	W-42	S	172	960	1280S
9	X-E1	N,S	474	1280N,#	2560N; 320S
10	13-3-1	H	5540	3840	5120H
11	13-3-11	S	2913	2560	5120S

* Average of separate readings by two persons.
#This sample showed a speckled pattern at the initial dilution of 1:40. It was not tested at 1:80, however it was tested at 1:160 and did not show a speckled pattern.

Ninety-six (96) serum samples, positive by both the VisiQuant ANA and the Bion ANA, were compared for ANA titers. Figure 2 shows the correlation with all patterns (Homogenous, Speckled, Nucleolar, Centromere and mixed) and Figure 3 shows the correlation with the Homogenous pattern only.

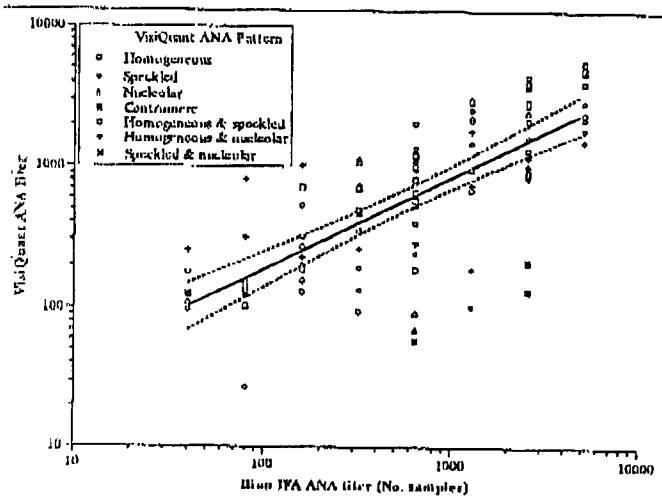

Figure 2. Scatter diagram showing correlation between VisiQuant titer (VT) and Bion IFA titer (BT) for 96 samples positive by both test. R=0.731, N=96, p<0.0001, Log VT= 0.964+0.654 x Log BT. The Linear Regression (solid line) and its 95% confidence intervals (dotted lines) are also shown.

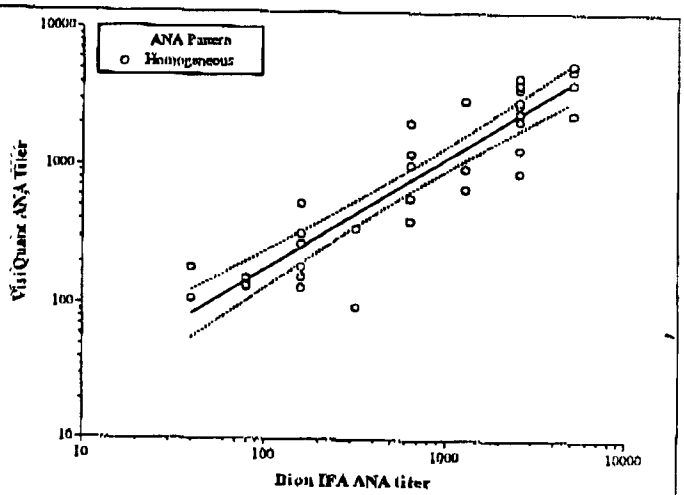

Figure 3. A scatter diagram showing correlation between VisiQuant titer (VT) and Bion IFA titer (BT) for 36 samples with homogenous ANA pattern. R=0.909, N=36, p<0.0001, Log VT=0.631+ 0.806 x Log BT. The Linear Regression (solid line) and its 95% confidence intervals (dotted lines) are also shown.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 0 4 2002

Ms. Radha Goolabsingh
Director of Quality Assurance and
Regulatory Affairs
Hyperion, Inc.
14100 S.W. 136th Street
Miami, Florida 33186

Re: k013213
Trade/Device Name: Hyperion VisiQuant™ ANA Test Kit
Regulation Number: 21 CFR § 866.5100
Regulation Name: Antinuclear Antibody Immunological Test System
Regulatory Class: II
Product Code: DHN
Dated: May 24, 2002
Received: May 28, 2002

Dear Ms. Goolabsingh:

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 such 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. 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" (21CFR 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) NUMBER (IF KNOWN): K013213

DEVICE NAME: Hyperion VisiQuant™ ANA Test Kit

INDICATIONS FOR USE: The Hyperion VisiQuant™ ANA Test Kit is intended for the visual determination of anti-nuclear antibodies (ANA's) immunofluorescence pattern(s) and the semi-quantitative measurement of ANA's in human serum with a single dilution as an aid in the in-vitro diagnosis of auto-immune and connective tissue diseases such as systemic lupus erythematosus (SLE) and Sjogren Syndrome.

Susan S. Alta.e

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013213

(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 ____

(Optional Format 1-2-96)